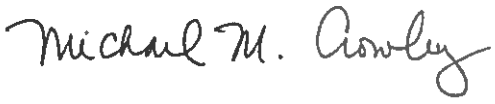
EXHIBIT C34

PORTIONS REDACTED PURSUANT TO DISCOVERY CONFIDENTIALITY ORDER DATED MARCH 1, 2017

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO ALL CASES**	**Civil Action No. 3:16-md-2738-FLW-LHG** **MDL No. 2328**

RULE 26 REPORT OF MICHAEL M. CROWLEY, PhD REGARDING THE FRAGRANCE CHEMICAL CONSTITUENTS IN JOHNSON & JOHNSON TALCUM POWDER PRODUCTS



Michael M. Crowley, PhD
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November 12, 2018

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Abbreviation	Definition or Explanation
Allergen	An allergen is a type of antigen that produces an abnormally vigorous immune response in which the immune system fights off a perceived threat that would otherwise be harmless to the body.
ACS	American Chemical Society
The Cosmetic Ingredient Review (CIR)	The Cosmetic Ingredient Review (CIR) reviews and assesses the safety of ingredients used in cosmetics in and publishes the results in the peer-reviewed scientific literature. The Cosmetic Ingredient Review was established in 1976 by the industry trade association (then the Cosmetic, Toiletry, and Fragrance Association, now the Personal Care Products Council (PCPC)..
CAS Number	CAS stands for "Chemical Abstracts Service," a division of the American Chemical Society that provides comprehensive electronic chemical information services. CAS assigns unique CAS Registry Numbers to chemical substances. The CAS Registry Number itself has no chemical significance.
CFR	Code of Federal Regulations. The Code of Federal Regulations is the codification of the general and permanent rules and regulations published in the Federal Register by the executive departments and agencies of the federal government of the United States.
CPSA	Consumer Product Safety Act, codified at 15 U.S.C. Section 2051–2084
FDA	The United States Food and Drug Administration
FEMA	The Flavor and Extract Manufacturers Association of the United States. FEMA is a trade association that has established expert panels that evaluate and make conclusions on the GRAS status of flavoring substances.
FEMA GRAS Program	In 1959, The Flavor and Extract Manufacturers Association of the United States (FEMA) took its initial actions to establish a program to assess the safety and "GRAS" (generally recognized as safe) status of flavor ingredients as described in the 1958 Food Additives Amendments to the Federal Food, Drug, and Cosmetic Act, the Federal law governing the regulation of flavors and other food ingredients. Since then, the FEMA GRAS program has become the longest-running and most widely recognized industry GRAS assessment program.
FFDCA	Federal Food, Drug, and Cosmetic Act, codified at 21 U.S.C. Section 321–397
FHSA	Federal Hazardous Substances Act, codified as amended at 15 U.S.C. Section 1261–1273
GRAS	Generally Recognized As Safe

Abbreviation	Definition or Explanation
	Generally recognized as safe is an American Food and Drug Administration (FDA) designation that a chemical or substance added to food is considered safe by experts, and so is exempted from the usual Federal Food, Drug, and Cosmetic Act (FFDCA) food additive tolerance requirements. The concept of food additives being "generally recognized as safe" was first described in the Food Additives Amendment of 1958, and all additives introduced after this time had to be evaluated by new standards. In the United States, the GRAS concept is one way in which the regulatory authority to use a food ingredient (other than color additives) can be determined with the other key path being through an application to the Food and Drug Administration for food additive status. GRAS status may be achieved either through the FDA's voluntary GRAS notification program (FDA, 1997) or through a properly conducted GRAS determination made by a private party. The statutory definition of GRAS has four key criteria, all of which must be met for a food ingredient to be considered generally recognized as safe and exempt from the requirements for food additive approval: • There must be general recognition of safety by qualified experts. • The experts must be qualified by training and experience to evaluate the substance's safety. • The experts must base their determination of safety on scientific procedures or on common use in food prior to 1958. • The determination of general recognition of safety must take into account the conditions of intended use for the substance, in other words its function in the food, e.g. flavoring.
GHS hazard statements	Hazard statements from the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).
Hypersensitivity	A state of altered reactivity in which the body reacts with an exaggerated immune response to a foreign agent
IFRA	International Fragrance Association
Inactive Ingredient Database (IID)	The Inactive Ingredient Database provides information on inactive ingredients present in FDA-approved drug products. In general, inactive ingredients on this list have been subject to extensive toxicology studies for a given route of administration.
Irritant	Irritation, in biology and physiology, is a state of inflammation or painful reaction to allergy or cell-lining

Abbreviation	Definition or Explanation
	damage. A stimulus or agent which induces the state of irritation is an irritant.
JECFA	The Joint Expert Committee on Food Additives (JECFA) is an international expert scientific committee that is administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO).
OSHA Hazard Communication Standard 29 CFR 1910.1200	Describes and classifies the hazards of all chemicals produced or imported. Contains information concerning the classified hazards transmitted to employers and employees. Intended to be consistent with the provisions of the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Revision 3.
Photosensitivity	Photosensitivity is the amount to which an object reacts upon receiving photons, especially visible light. In medicine, the term is principally used for abnormal reactions of the skin, and two types are distinguished, photoallergy and phototoxicity.
Phototoxicity	Phototoxicity, also called photoirritation, is a chemically induced skin irritation, requiring light that does not involve the immune system.
PubChem	A database of chemical molecules and their activities against biological assays. The system is maintained by the National Center for Biotechnology Information, a component of the National Library of Medicine, which is part of the United States National Institutes of Health.
QRA	Quantitative Risk Assessment (QRA), an exposure based risk assessment system developed by IFRA to determine safe use levels of fragrances in consumer products.
REXPAN	RIFM Expert Panel. REXPAN examines the dermal effects, systemic toxicity and environmental consequences of the use of and exposure to fragrance materials
RIFM	Research Institute for Fragrance Materials, the science center of IFRA
RTECS	Registry of Toxic Effects of Chemical Substances. RTECS is a definitive toxicological database with supplemental information pertinent to both the chemical industry and the occupational safety and health community. This technical data is needed to assess workers' exposures to chemicals, particularly to lesser-known-and-used chemical substances. OSHA has designated RTECS as a primary source for toxicity data for Material Safety Data Sheets in its Hazard Communications Rule. In recent years RTECS has grown to include more than 160,000 chemicals. The toxicological data are organized into six fields: primary irritation, mutagenic effects, reproductive

Abbreviation	Definition or Explanation
	effects, tumorigenic effects, acute toxicity and multiple dose toxicity.
SCHER	Scientific Committee on Health and Environmental Risks is an independent scientific committee managed by the Directorate-General for Health and Consumer Protection of the European Commission, which provide scientific advice to the Commission on issues related to consumer products.
Sensitization	The preliminary exposure of a person to an allergen that leads to antibody production by the immune system and, on subsequent exposure, to an allergic or hypersensitivity reaction. Inducing an adaptive response in the immune system and or exposure to allergen that results in the development of hypersensitivity. In this sense, sensitization is the term more often in usage for induction of allergic responses.
ToxNet	TOXNET® (TOXicology Data NETwork) is a group of databases covering chemicals and drugs, diseases and the environment, environmental health, occupational safety and health, poisoning, risk assessment and regulations, and toxicology. It is managed by the Toxicology and Environmental Health Information Program (TEHIP) in the Division of Specialized Information Services (SIS) of the National Library of Medicine (NLM).
TSCA	Toxic Substances Control Act
UNII	UNII stands for "Unique Ingredient Identifier". The UNII is a part of the joint United States Pharmacopeia (USP)/FDA Substance Registration System (SRS), which has been designed to support health information technology initiatives by providing unique identifiers for substances in drugs, biologics, foods, and devices based on molecular structure and/or descriptive information. The SRS is used to generate permanent, unique, unambiguous identifiers for substances in regulated products

1 EXECUTIVE SUMMARY

This report addresses the fragrance components of Johnson and Johnson's talcum powder products and the question of whether these substances contribute to the development of ovarian cancer.

This report addresses these questions:

- Are the fragrance chemicals in compliance with governmental and industry standards?
- Can the fragrance chemicals in the talcum powder products contribute to the inflammatory properties, toxicity, and potential carcinogenicity of the products?

To answer these questions, I conducted an independent review of the regulatory standards, safety, toxicological, medical, pharmacological and other scientific literature concerning the fragrance chemicals present in Johnson's Baby Powder and Shower to Shower talcum products. Although I have experience in the vaginal administration of pharmaceutical products and its implications, I was asked, for the purposes of this report, to assume that talcum powder can migrate from the perineum to the upper genital tract. It is my understanding that other expert witnesses will address this topic.

Johnson's Baby Powder contains a mixture of 141 fragrance chemicals, some of which are extracts that are themselves a mixture of chemicals. Likewise, the Shower to Shower product contains a fragrance mixture comprising 53 fragrances, some of which are mixtures themselves. Of the 53 fragrance chemicals in Shower to Shower, 19 are present in Baby Powder (34 fragrance chemicals are unique to Shower to Shower). Thus, there are at least 175 fragrance chemicals between the two products.

The fragrance chemicals were examined for compliance to government and industry regulatory standards. Twenty-two (22) fragrance chemicals in the Johnson's Baby Powder (15.6% of those present) and twenty (20) fragrance chemicals in the Shower to Shower product (37.7%) were identified with a regulatory concern (Table 1).

There are chemicals in the fragrance mixture in the Johnson & Johnson talcum products that do not have an established government or industry standard, are not fragrances, or are not approved for use in a fragrance. For example, Myroxylon Pereirae (Balsam Peru) Oil, present in Baby Powder, is prohibited by the International Fragrance Association (IFRA) for use as a fragrance ingredient and on the EU Annex ii of chemicals prohibited from cosmetics in Europe. Para-cresol is not permitted in cosmetics according to the Cosmetic Ingredient Review Expert Panel.

In addition, Methyl Hydrogenated Rosinate is present in both the Baby Powder and Shower to Shower products. Methyl Hydrogenated Rosinate is not a fragrance, does not have an IFRA standard and is not listed by CIR.

Accordingly, in response to the first question, in my opinion the fragrance chemicals are not in compliance with governmental and industry standards.

The fragrance chemicals were reviewed for pharmacological activity, safety and toxicity concerns. Thirty-four chemicals were identified in Johnson's Baby Powder (24%) and twelve chemicals in the Shower to Shower product (20%) with safety and toxicology concerns (Table 1). I identified several chemicals in the fragrance mixture used by J&J in the talcum products with studies, in vitro and in vivo, published in peer reviewed journals demonstrating carcinogenicity, developmental or reproductive toxicity, genotoxicity, and or mutagenicity.

Four chemicals in Johnson's Baby Powder product have been identified by the International Agency for Research on Cancer (IARC) as potential carcinogens. "Benzene, ethenyl-", also known as Styrene [1], has been implicated as reproductive toxicant, neurotoxicant, and has been demonstrated to be a carcinogen in vivo and in vitro. Styrene is listed as such by several governmental and regulatory bodies (RTECS, Prop 65 among others). The National Toxicology Program considers styrene to be "reasonably anticipated to be a human carcinogen" (The National Toxicology Program (NTP), 2016). The FDA recently delisted Styrene from the Code of Federal Regulations as a food additive because FDA believed its use had been abandoned.

In addition, the U.S. Environmental Protection Agency considers p-cresol (also known as 4-methylphenol) to be "possibly carcinogenic"(U.S. Environmental Protection Agency, 1990). The International Agency for Research on Cancer (IARC) has stated that coumarin, eugenol, and d-limonene are "not classifiable" as to their carcinogenicity (Group 3). The remainder of the fragrance chemicals in the Baby Powder talcum product have not been evaluated by IARC as to their carcinogenicity.

Three fragrance chemicals added to J&J's Shower to Shower talcum product are included in the IARC monographs as possible carcinogens. Benzophenone has been classified by IARC as a Group 2B possible human carcinogen (International Agency for Research on Cancer (IARC), 2013b). Coumarin and eugenol are "not classifiable" as to their carcinogenicity (Group 3). In addition, Musk ketone is suspected of being a carcinogen, and has been classified as a Category 3 carcinogen by the Scientific Committee on Health and Environmental Risks (SCHER) in Europe. The remainder of the fragrance chemicals in the Shower to Shower product have not been evaluated by IARC as to their carcinogenicity.

Table 1 **Number of Fragrance Chemicals Added to Johnson & Johnson Talcum Products With Regulatory, Safety and Toxicology Concerns (Percent of Total Fragrance Chemicals Present)**

Category	Baby Powder	Shower to Shower
Regulatory Concerns	22 (15.6%)	20 (37.7%)
Safety /Toxicology Concerns	35 (24.8%)	12 (20.8%)

The fragrance chemicals were reviewed to identify those that are classified as irritants, skin irritants and eye irritants according to the Globally Harmonized System of Classification and Labelling of Chemicals in accordance with 29 CFR 1910 (OSHA HCS). More than 40% of the chemicals present in the fragrance mixture used by J&J in the talcum products are classified as irritants, greater than 70% are skin and eye irritants, and about 25% are sensitizers or allergens (Table 2).

Most of these fragrances were granted approval for cosmetic use based upon single administration dermal studies (i.e. the fragrance is applied to an animal once and examined for 24 hours). Few of the fragrance chemicals have been investigated with a Human Repeat Insult Patch Test (HRIPT), a study with repeat administration to the skin (i.e. daily administration for 1 week). In 2008, the fragrance industry recognized this shortcoming and is re-examining fragrance chemicals to identify issues and verify safe levels of exposure (Api et al., 2008).

Some fragrances were identified as eye irritants because the eye is a mucous membrane, as is the vagina. Fragrance chemicals that irritate the eye are also likely to irritate the vaginal mucosa.

[1] Styrene was replaced by Styrax Oil in April, 2014 according to Exhibit 3 "CHANGES TO JOHNSON'S BABY POWDER FRAGRANCE INGREDIENTS"

Table 2 **Number of Fragrance Chemicals Added to Johnson & Johnson Talcum Products Classified as Irritants, Sensitizers and Allergens (Percent of Total Fragrance Chemicals Present)**

Category	Baby Powder	Shower to Shower
Irritants	58 (41.1%)	25 (47.2%)
Skin Irritants	110 (78.0%)	44 (83.0%)
Eye Irritants	104 (73.8%)	40 (75.5%)
Sensitizers	39 (27.7%)	16 (30.2%)
Allergens	35 (24.8%)	16 (30.2%)

The International Fragrance Association (IFRA) is the official self-regulatory representative body of the fragrance industry worldwide. IFRA's main purpose is to ensure the safety of fragrance materials through a dedicated science program and publishes a list of usage standards for fragrance materials, limiting or prohibiting the use of ingredients, based on the findings of the Research Institute of Fragrance Materials (RIFM). RIFM gathers data regarding the safety of fragrance materials.

The fragrance chemicals were reviewed to identify those that are classified with IFRA Critical Effects, limitations for baby powder and talcum products (a Category 5 Limitation) and dermal exposure limits. More than 25% of the chemicals present in the fragrance mixture used by J&J in the talcum products have an IFRA Critical Effect, and greater than 15% have exposure limitations in baby powder and talcum products (Table 3).

Table 3 **Number of Fragrance Chemicals Added to Johnson & Johnson Talcum Products with IFRA Critical Effects and Exposure Limitations (Percent of Total Fragrance Chemicals Present)**

Category	Baby Powder	Shower to Shower
IFRA Critical Effects	39 (27.7%)	15 (28.3%)
IFRA Category 5 Limits	23 (16.3%)	13 (24.5%)
IFRA Exposure Limits	25 (17.7%)	9 (17.0%)

The fragrance chemicals were reviewed to identify those listed on the Inactive Ingredient Database (IID) maintained by the US Food and Drug Administration. The IID provides information on inactive ingredients present in FDA-approved drug products. The inactive ingredients on this list have been subject to extensive toxicology studies for a given route of administration (i.e. oral, injected or vaginal).

About 20% of the chemicals present in the fragrance mixture used by J&J in the talcum products are listed on the IID, about 11% are present in an approved drug product for topical administration to the skin, and less than 4% are present in an approved drug product for vaginal administration (Table 4).

Table 4 **Number of Fragrance Chemicals Added to Johnson & Johnson Talcum Products Listed on the FDA IID (Percent of Total Fragrance Chemicals Present)**

Category	Baby Powder	Shower to Shower
IID Listed	26 (18%)	11 (21%)
IID Listed for Topical Administration	9 (6%)	6 (11%)
IID Listed for Vaginal Administration	1 (1%)	2 (4%)

FDA and EFSA consider oral administration for flavors. IFRA and CIR consider topical administration (i.e. application to the skin) for fragrances and cosmetic ingredients. In this matter, the talcum products were applied to the perineal area. The transport of talcum products into the vaginal cavity and exposure to the vagina, endometrium, fallopian tubes, and ovaries would be an unintended consequence of perineal application of these products. The safety margins of the 175 fragrance chemicals were determined for foods (oral administration) or cosmetics (topical application to the skin), except for the three fragrance chemicals listed on the FDA IID present in an approved drug product administered to the vagina. In other words, only three of the 175 fragrance chemicals have been investigated for safety in the vagina. The fragrances that are irritants (particularly mucosal irritants), sensitizers and allergens can cause inflammation and oxidative stress. Accordingly, in my opinion, the fragrance chemicals in the Johnson & Johnson talcum powder products contribute to the inflammatory properties, toxicity, and potential carcinogenicity of these products.

2 QUALIFICATIONS

I earned a B.S. in Chemistry from the University of Missouri–St. Louis, an M.A. in Organic Chemistry from Washington University in St. Louis and a Ph.D. in Molecular Pharmaceutics from the University of Texas.

I am currently the President of Theridian Technologies, LLC, a pharmaceutical development consulting firm established in March 2009. I have served as a consultant to more than 50 companies, mostly in the pharmaceutical industry. I primarily consult in the area of proof of concept, formulation and product development, drug delivery and clinical development, including generation of FDA regulatory submissions.

In 2015, I co-founded Oticara, Inc., a startup pharmaceutical company developing novel drug products for the treatment for infectious disease. I also serve on the Board of Directors for Texas EnteroSorbents, a life science company.

From 2003 to 2009, I was an owner (Member) and employed by PharmaForm, LLC, a contract research organization providing formulation and drug product development services. I served as Vice President, Business Development; Vice President, Quality Control and Analytical Services; and Vice President, Drug Delivery Technology & Manufacturing. From 1995 until 2000, I worked in research and development at Mission Pharmacal Company in San Antonio, Texas. From 1992 to 1995, I worked as a chemist at Warner-Jenkinson Company in St. Louis, Missouri. In these roles, I worked on the development of pharmaceutical formulations, nutritional supplements and food products.

During my career, I have developed over 50 formulations that have been tested in human clinical studies. I have authored or co-authored over 15 clinical study protocols, including the pharmacy manual, daily diary, investigators brochure, informed consent form, adverse event tracking log, and drug dispensation log. I have been present in the clinic when participants have been dosed and have audited clinical study sites.

I have authored or co-authored over 30 published articles and abstracts and four book chapters relating to my work. Among my publications are a significant number of articles concerning pharmaceutical formulation techniques in general, and the effects of certain formulation techniques and excipients. I also am an inventor on five United States patents as well as a number of foreign patents and pending applications relating to my work.

One of my articles, "Pharmaceutical Applications of Hot-Melt Extrusion: Part I" published in Drug *Development and Industrial Pharmacy* in 2007, was the most downloaded manuscript from the publisher in 2011 and 2012.

I have served as a reviewer for many peer reviewed journals, including the *Journal of Pharmaceutical Sciences, Drug Development and Industrial Pharmacy, European Journal of Pharmaceutics and Biopharmaceutics, Journal of Pharmacy and Pharmacology, European Journal of Pharmaceutics, Pharmaceutical Research, International Journal of Pharmaceutics, Journal of Microencapsulation, S.T.P. Pharma Sciences (France), Pharmaceutical Development and Technology, Journal of Controlled Release*, and *AAPS PharmSciTech.*

My current research focuses on the formulation, development, optimization, and delivery of small organic compounds, peptides and proteins by a variety of technologies, including hot melt extrusion and thermal processing techniques, depot drug delivery, oral drug delivery, pulmonary drug delivery, implantable drug delivery and abuse deterrent drug delivery.

In the last five years, I have testified as an expert by deposition in the following cases:

- *Grünenthal, GmbH et al. v. Teva Canada Ltd. et al.*, Court File No. T-1009-14 (Can. Fed. Ct.).
- *In Re CIPRODEX*, Consolidated Civil Action No. 3:15-cv-05756 (PGS) (DEA) (D.N.J.).

A copy of my curriculum vitae is attached as Appendix C to this Report. I am being compensated for my work at a rate of $600 per hour.

3 SOURCES CONSIDERED

A List of sources considered during generation of this report is provided in Table 5. References from the scientific literature are provided in Section 7.

Table 5 Sources Considered

Source	Link / Background
Canadian Cosmetic Ingredient Hotlist: Prohibited and Restricted Ingredients	https://www.canada.ca/en/health-canada/services/consumer-product-safety/cosmetics/cosmetic-ingredient-hotlist-prohibited-restricted-ingredients/hotlist.html
Cell Proliferation	https://onlinelibrary.wiley.com/journal/13652184
CFR - Code of Federal Regulations Title 21	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm
ChemSec SIN List	http://chemsec.org/sin-list/
ChemSpider	http://www.chemspider.com/

Source	Link / Background
Cosmetic Ingredient Review	https://www.cir-safety.org/ingredients
Educational report of Dr. Thomas Dydek, PhD, DABT, PE regarding the cancer-causing constituents of defendants' talcum powder products	
The EFSA Journal (The European Food Safety Authority Journal)	https://efsa.onlinelibrary.wiley.com/journal/18314732
Environmental and Molecular Mutagenesis	https://onlinelibrary.wiley.com/journal/10982280
EU Annex ii: Chemicals prohibited from cosmetics in the EU	http://ec.europa.eu/growth/tools-databases/cosing/pdf/COSING_Annex%20II_v2.pdf
European Union Endocrine Disruptors Priority List	http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm
Evaluation Of Certain Food Additives And Contaminants, WHO Technical Report Series, Fifty-seventh report of the Joint FAO/WHO Expert Committee on Food Additives, World Health Organization Geneva, 2002	http://www.who.int/foodsafety/publications/monographs/en/
EPA Distributed Structure-Searchable Toxicity (DSSTox) Database	https://www.epa.gov/chemical-research/distributed-structure-searchable-toxicity-dsstox-database
FDA Inactive Ingredient Search for Approved Drug Products	https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm
FDA The Substances Added to Food Inventory	https://www.accessdata.fda.gov/scripts/fdcc/?set=FoodSubstances
FDA Substance Registration System	https://fdasis.nlm.nih.gov/srs/
FEMA	https://www.femaflavor.org/
FEMA Flavor Ingredient Library	https://www.femaflavor.org/flavor-library
Food and Chemical Toxicology	https://www.journals.elsevier.com/food-and-chemical-toxicology
The Food and Agriculture Organization (FAO) of the United Nations Online Edition: "Specifications for Flavourings"	http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-flav/en/
The Good Scents Company Information System	http://www.thegoodscentscompany.com/index.html
International Journal of Toxicology	http://journals.sagepub.com/home/ijt
IFRA	http://www.ifraorg.org/
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JNJ 000350166 – 236	
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JNJTALC000113055	
JNJTALC000126887	
JNJTALC000383896	
PCPC_MDL00012948	
PROTECTED - Powder Fragrance Ingredients	Supplemental Answer to Plaintiffs' Second Set of Interrogatories No. 19, Ingham, et al., v. Johnson & Johnson, et al Attorney Eyes Only Documents (Exhibit 1, Exhibit 2, and Exhibit 3)
Monographs on Fragrance Raw Materials A Collection of Monographs originally appearing in Food and Cosmetics Toxicology An International Journal, Edited by D. L. J. Opdyke. Pergamon Press New York 1979 eBook ISBN: 9781483147970	https://www.elsevier.com/books/monographs-on-fragrance-raw-materials/opdyke/978-0-08-023775-6
National Library of Medicine Drug Information Portal	https://druginfo.nlm.nih.gov/drugportal/
Personal Care Products Council (formerly CTFA)	https://www.personalcarecouncil.org/
PubChem	https://pubchem.ncbi.nlm.nih.gov/
Regulatory Toxicology and Pharmacology	https://www.journals.elsevier.com/regulatory-toxicology-and-pharmacology
Research Institute for Fragrance Materials (RIFM)	https://www.rifm.org/
Registry of Toxic Effects of Chemical Substances (RTECS)	https://www.cdc.gov/niosh/rtecs/default.html
ToxNet	https://toxnet.nlm.nih.gov/
Women's Voices for the Earth (WVE)	https://www.womensvoices.org/fragrance-ingredients/fragrance-chemicals-assigned-the-signal-word-warning-by-un-ghs/

4 FRAGRANCE CHEMICALS IN JOHNSON & JOHNSON BABY POWDER PRODUCT

The Johnson & Johnson Baby Powder product contains 141 fragrance chemicals. Some of these fragrances are themselves a mixture of chemicals.

4.1 Unidentified Fragrance Chemicals

One fragrance chemical could not be identified: Caprylyl Alcohol. A Google search did not return definitive information to enable identification. It is likely a typographical error in the above document,

and it is likely meant to be Caprylic Alcohol, which is a known fragrance. This fragrance chemical is not included in the analysis below since it cannot be identified definitively.

4.2 Fragrance Chemical Regulatory Review

In the U.S., manufacturers of consumer products, and owners of chemical formulations (such as fragrances) in those products, are not required to disclose all ingredients to consumers (Steinemann, 2009). The product label for fragranced products regulated under the Federal Food, Drug, and Cosmetic Act ("FFDCA") needs to list the word "fragrance," but not the ingredients in the fragrance (21 C.F.R. Section 701.3). The label may also list a similar term, such as "perfume," "parfum," "natural fragrance," "pure fragrance," "organic fragrance," etc., although those terms do not have a legal definition.

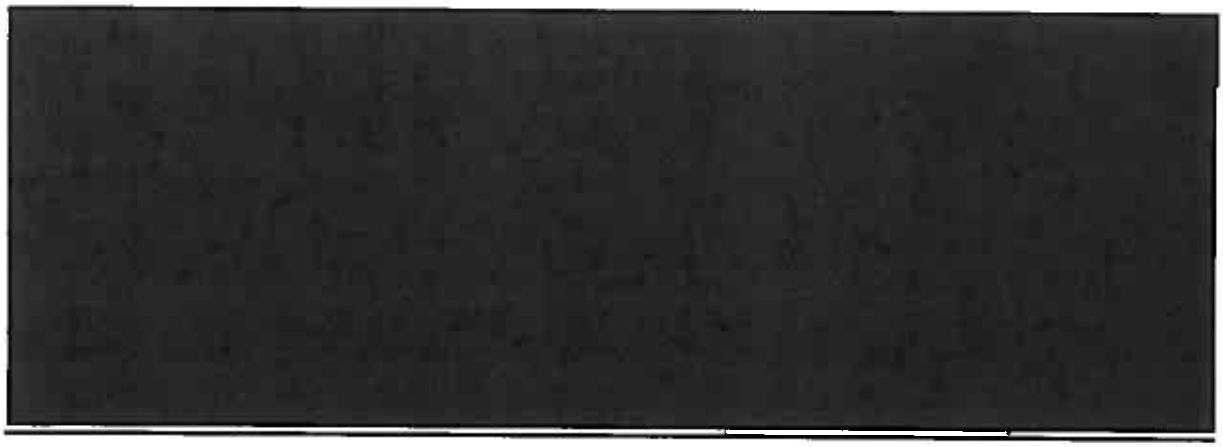
Regulation of consumer products largely falls under the Consumer Product Safety Act ("CPSA"). The CPSA does not require disclosure of all ingredients in products. Instead of listing ingredients, a manufacturer can provide other information on a product, such as a warning label. Similarly, the Federal Hazardous Substances Act (FHSA) requires warning labels for hazardous substances, but does not require that all ingredients be disclosed on the product's label. Ingredients can also be exempt from disclosure through "trade secrets" protection. Under the FFDCA, fragrance ingredients that qualify as trade secrets may be listed as "and other ingredients" without disclosing the ingredients.

The Toxic Substances Control Act (TSCA) of 1976 authorizes the EPA to secure information on all new and existing chemicals (or mixtures) sold in interstate commerce.

A regulatory review of the fragrance chemicals was performed. Twenty-three (23) fragrance chemicals in the Johnson & Johnson Baby Powder product were identified that are either (1) not listed in Title 21 of the Code of Federal Regulations, (2) not approved for fragrance of flavor use, (3) not permitted for cosmetic use, (4) requires warnings, (5) are not permitted for use on the body (6) absence of an IFRA Standard (7) absence of a CIR listing, or a CIR listing as unsafe or insufficient data to support safety.

A summary of the fragrance chemicals with regulatory concerns is provided in Table 6. A comparison of the number of fragrance chemicals with regulatory concerns to the total number of fragrance chemicals is provided in Figure 1.

Table 6 Fragrance Chemicals Added to Johnson & Johnson Baby Powder Product with Regulatory Concerns



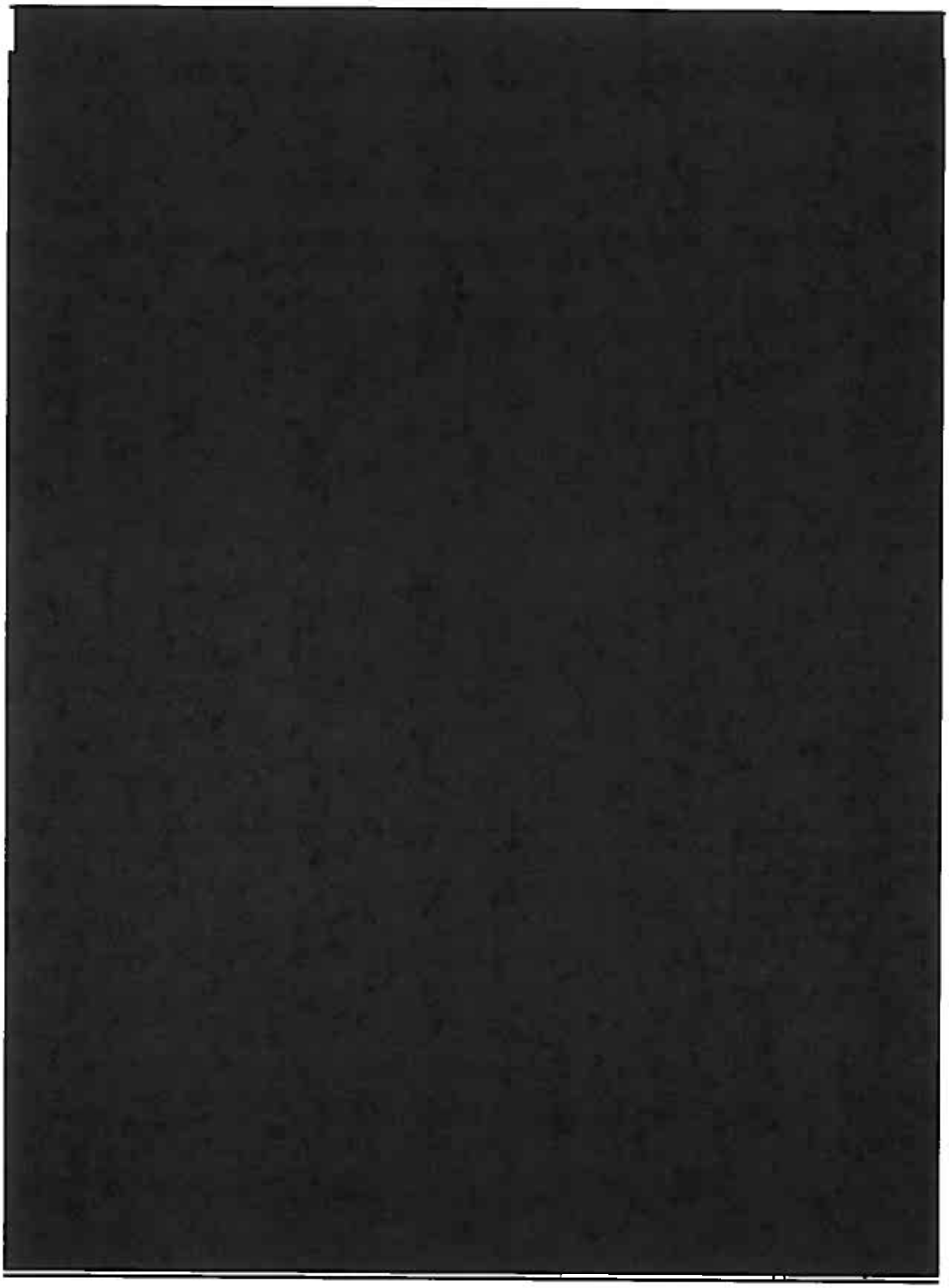


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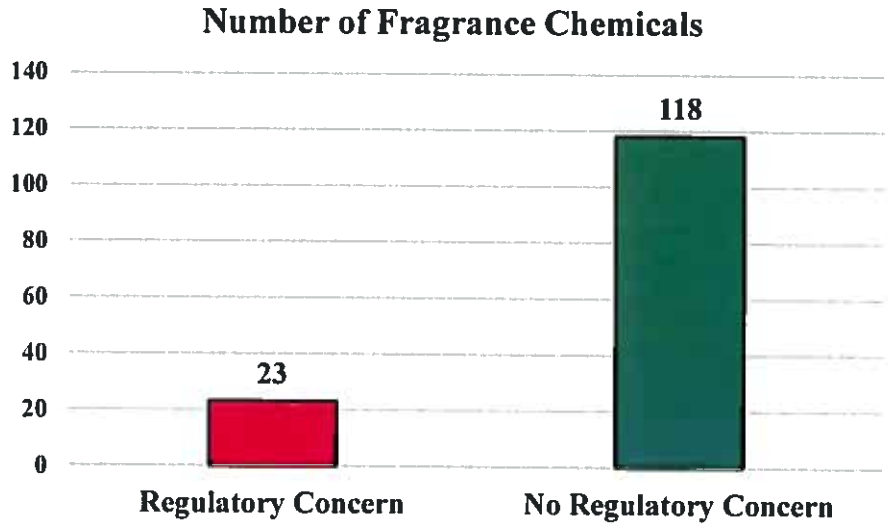
Figure 1 **Fragrance Chemicals with Regulatory Concerns**



4.3 Fragrance Chemical Safety and Toxicology Review

The RIFM Expert Panel ("REXPAN") examines the dermal effects, systemic toxicity and environmental consequences of the use of and exposure to fragrance materials (D. R. Bickers et al., 2003). The REXPAN approach involves grouping more than 2,600 discrete ingredients into classes, based on chemical structures. Research sponsored by RIFM, data supplied by member companies, and relevant published reports from many sources are considered during hazard characterization. This process results in well-documented conclusions which are provided to the International Fragrance Association (IFRA) as the basis for consideration of a new or existing Fragrance Material Standard. The RIFM's methods are modeled after the National Academy of Sciences' (NRC) Elements of Risk Assessment and Risk Management (National Research Council Committee on Risk Assessment of Hazardous Air, 1994).

The Cosmetic Ingredient Review was established in 1976 by the industry trade association (then the Cosmetic, Toiletry, and Fragrance Association, now the Personal Care Products Council (PCPC). PCPC funds the CIR, and CIR does not usually review fragrances, colors, or flavorings.

The fragrance chemicals in Johnson's Baby Powder Product were reviewed for safety and toxicology. Thirty-five (35) fragrance chemicals were found to be listed on the RTECS list (Registry of Toxic Effects of Chemical Substances maintained by the Center for Disease Control) or had safety in use concerns.

Four chemicals in Johnson's Baby Powder product have been identified by the International Agency for Research on Cancer (IARC) as potential carcinogens. "Benzene, ethenyl-", also known as Styrene, has been implicated as reproductive toxicant, neurotoxicant, and has been demonstrated to be a carcinogen in vivo and in vitro. It is my understanding that Styrene was removed from Johnson's Baby Powder in April, 2014. Styrene is listed as such by several governmental and regulatory bodies (RTECS, Prop 65 among others). The National Toxicology Program considers styrene to be "reasonably anticipated to be a human carcinogen" (The National Toxicology Program (NTP), 2016). The FDA recently delisted Styrene from the Code of Federal Regulations as a food additive because FDA believed its use had been abandoned.

In addition, the U.S. Environmental Protection Agency considers p-cresol (also known as 4-methylphenol) to be "possibly carcinogenic" (U.S. Environmental Protection Agency, 1990). The International Agency for Research on Cancer (IARC) has stated that coumarin, eugenol, and d-limonene are "not classifiable" as to their carcinogenicity (Group 3). The remainder of the fragrance chemicals in Baby Powder have not been evaluated by IARC as to their carcinogenicity.

Styrene was recently removed from use in foods by FDA (U.S. Food and Drug Administration, 2018). Notably, the FDA noted that use of Styrene as a synthetic flavoring substance and adjutant in food has been abandoned.

Several chemicals in the fragrance mixture used by J&J in the talcum products were identified with in vitro and in vivo studies published in peer reviewed journals demonstrating carcinogenicity, developmental or reproductive toxicity, genotoxicity, and or mutagenicity. While these studies are not definitive that the same effects would be observed in humans, they are indicators of biological activity.

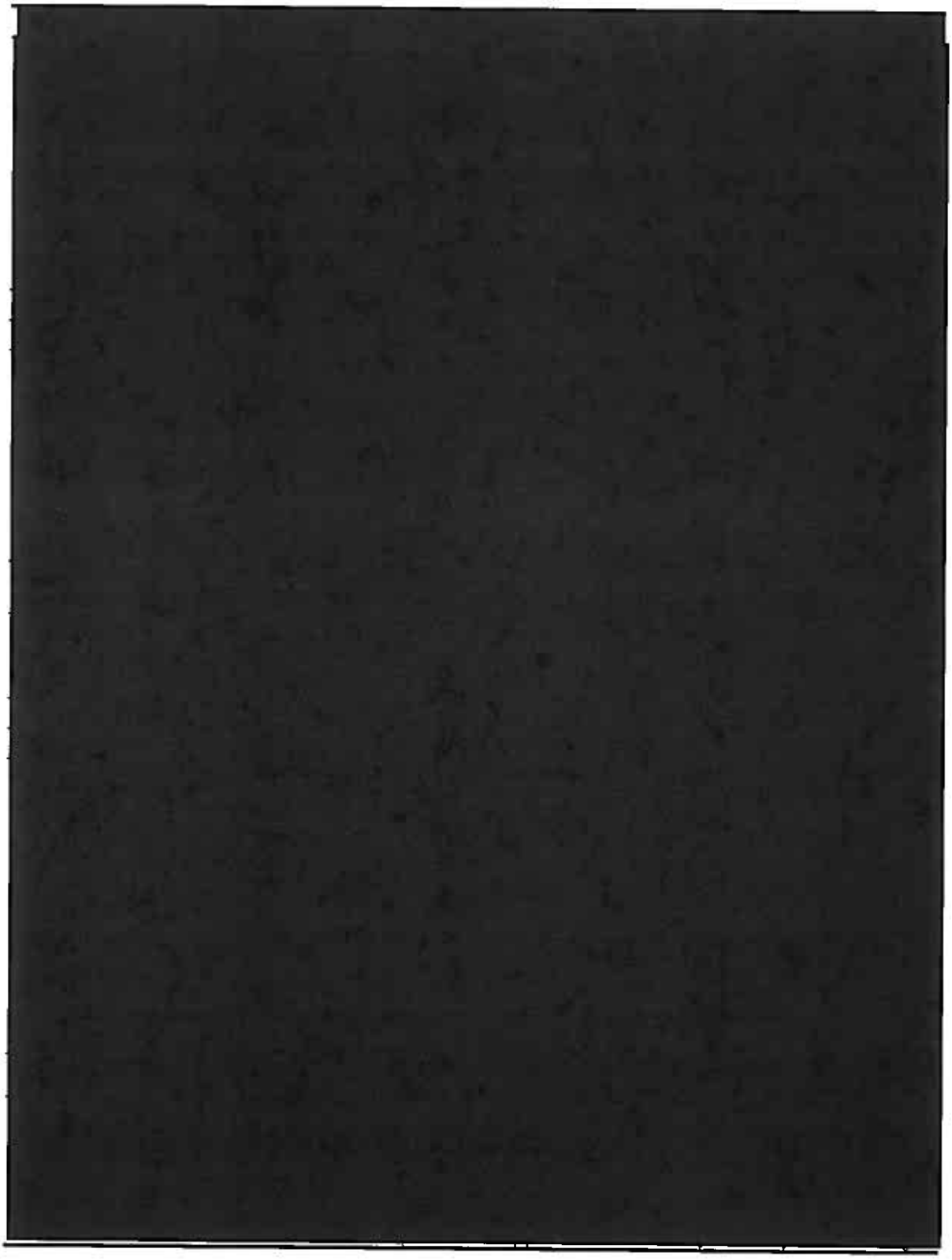
For example, The European Food Safety Authority concluded that Ethyl 3-methyl-3-phenyloxirane-2-carboxylate, also known as Ethyl Methylphenylglycidate, "there is substantial evidence of a genotoxic potential from the available in vitro and in vivo studies (European Food Safety Authority, 2009).

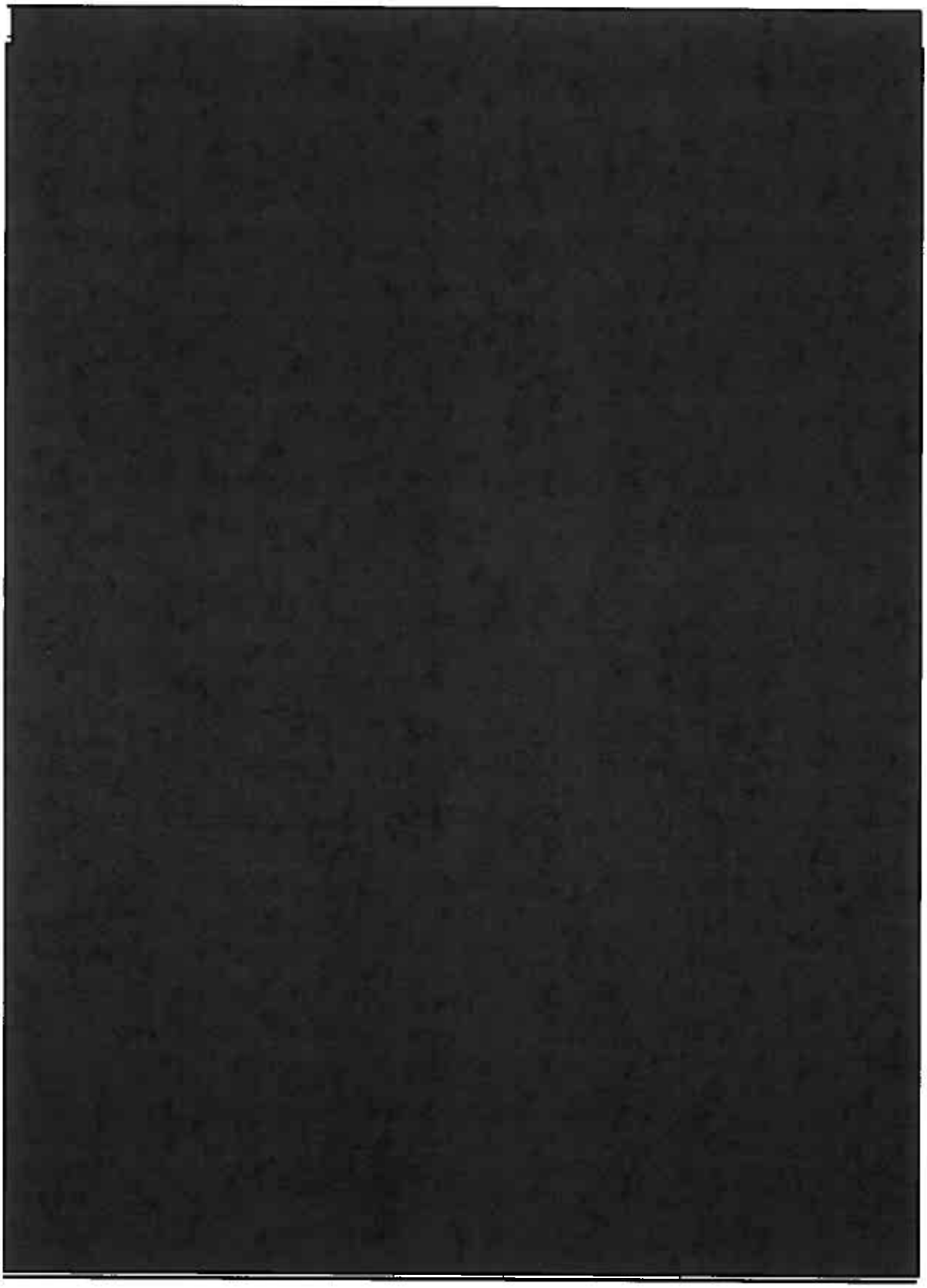
The CIR Expert Panel concluded there is insufficient information available to support the safety of Juniperus Communis Fruit Oil for use in cosmetics (Cosmetic Ingredient Review Expert Panel, 2001b).

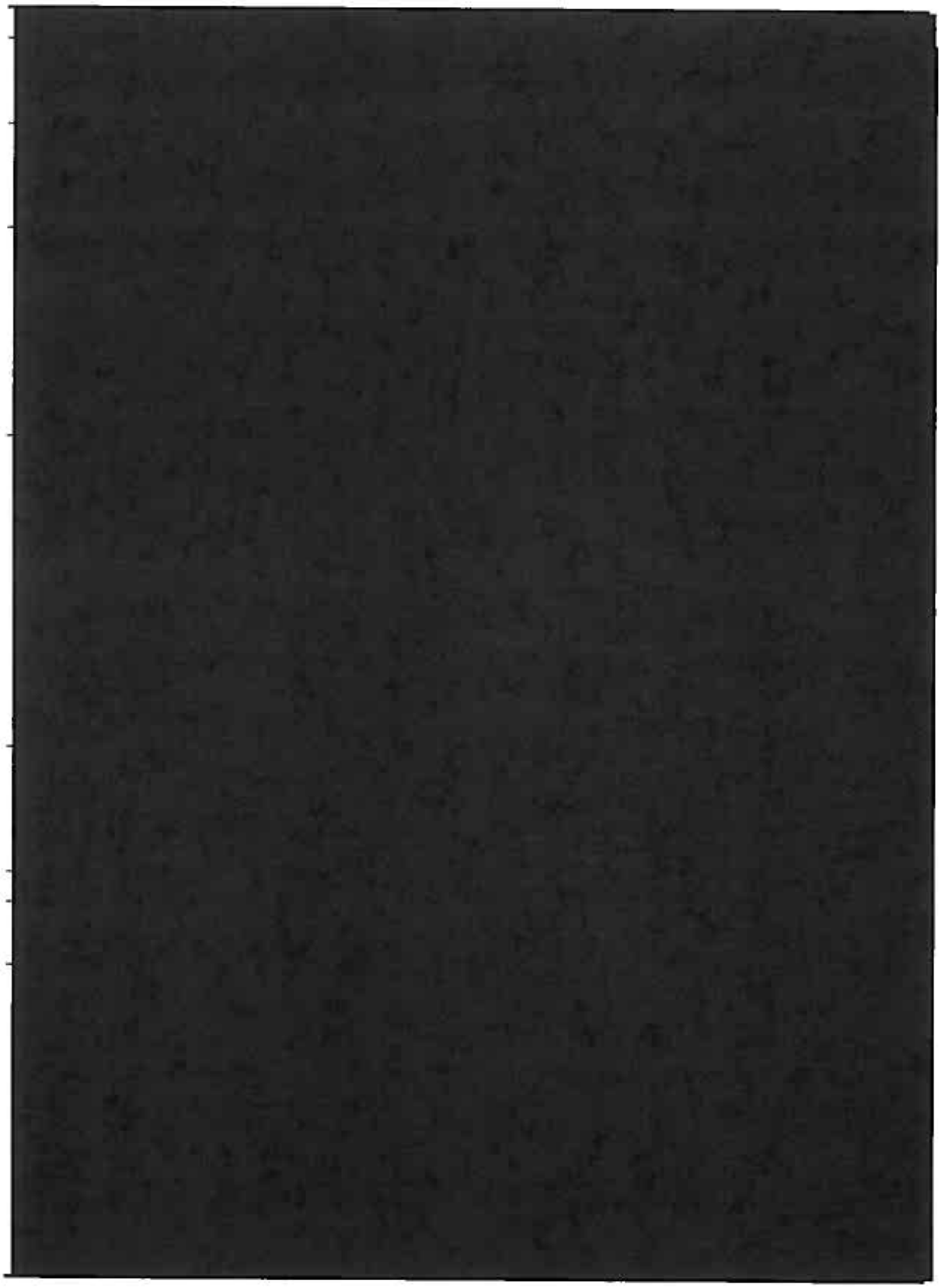
Similarly, the CIR Expert Panel found that p-Cresol was considered positive for inducing chromosomal aberrations in CHO cells under both activation and nonactivation conditions, and the available data are insufficient to support the safety in cosmetics (Cosmetic Ingredient Review Expert Panel, 2006). Boutwell and Bosch reported that p-Cresol was co-carcinogenic and promoted tumors on mouse skin (Boutwell & Bosch, 1959).

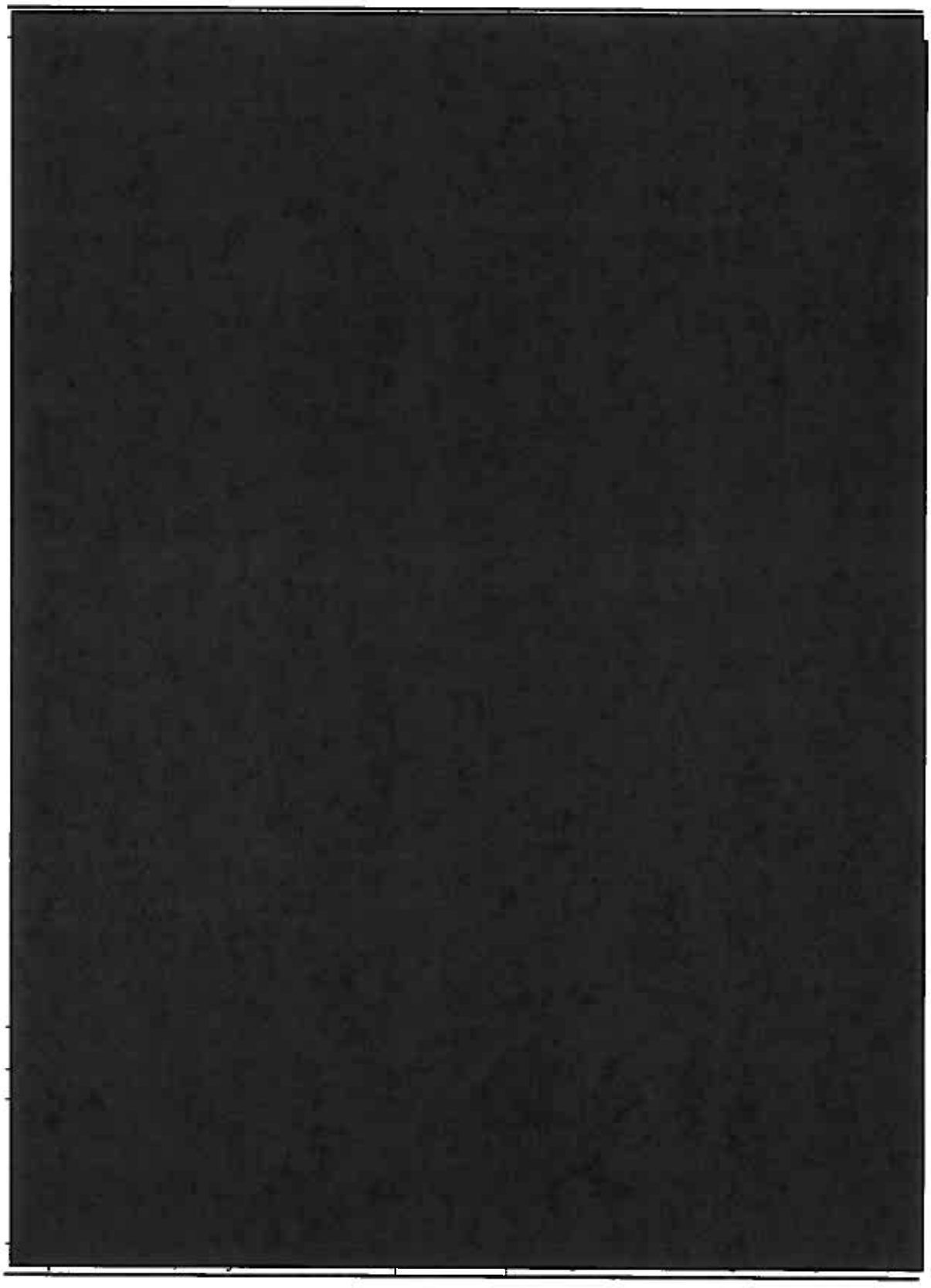
A summary of the findings is provided in Table 7 and a comparison of the number of fragrance chemicals with safety and toxicology concerns to the total number of fragrance chemicals in the product is provided in Figure 2.

Table 7 **Fragrance Chemicals Added to Johnson & Johnson Baby Powder Product on the RTECS List and or Toxicity Concerns**



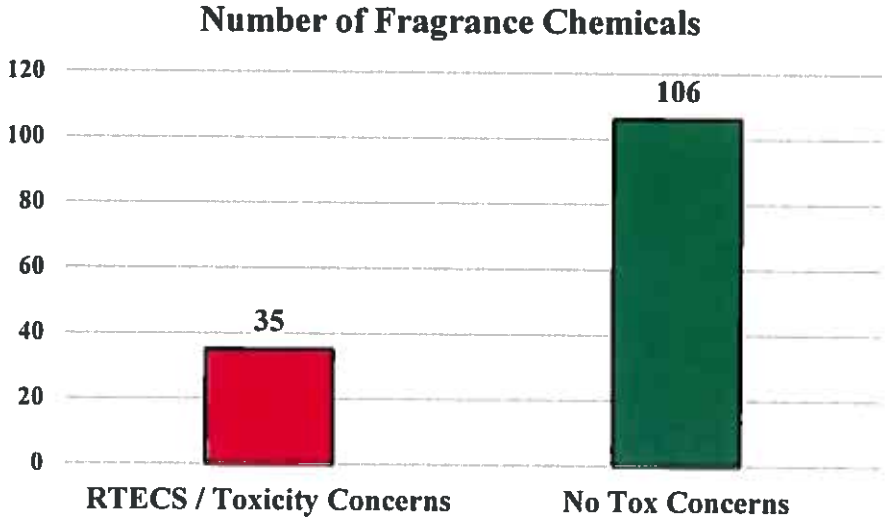






[redacted]

Figure 2 **Fragrance Chemicals with Toxicity Concerns**



4.4 Fragrance Chemicals Classified As Irritants

A stimulus or agent which induces the state of irritation is designated an "irritant". In biology and physiology, irritation is a state of inflammation or a painful reaction to allergy or cell-lining damage.

The fragrance chemicals were reviewed to identify those that are classified as irritants ("Xi"), skin irritants and eye irritants according to the Globally Harmonized System of Classification and Labelling of Chemicals in accordance with 29 CFR 1910 (OSHA HCS).

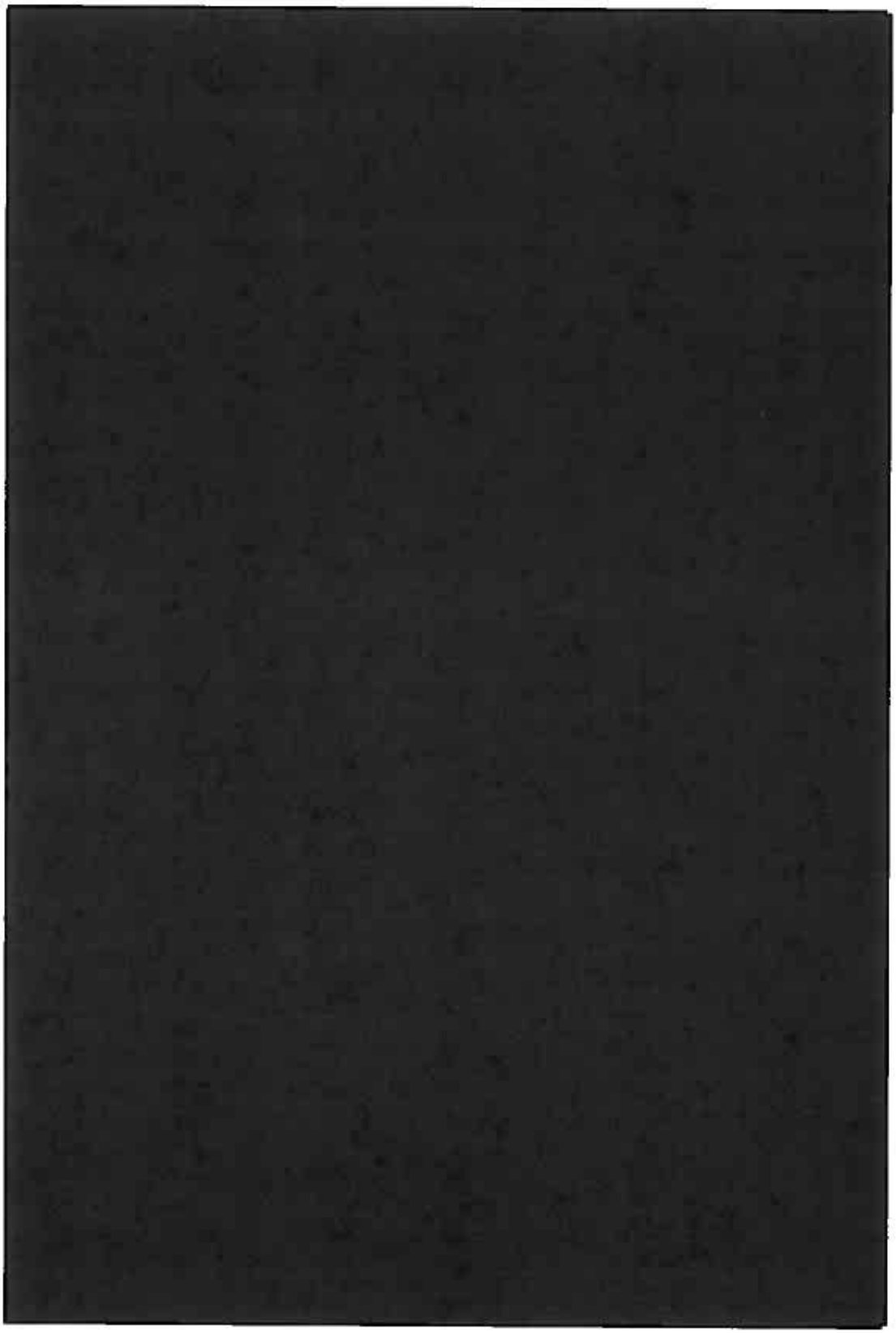
The "Xi" designation is used on Material Safety and Data Sheets (MSDS) for non-corrosive substances and preparations which, through immediate, prolonged or repeated contact with the skin or mucous membrane, may cause inflammation. Fragrance Chemicals with R36, H315 or equivalent designations were classified as skin irritants. Fragrance Chemicals with R38, H319 or equivalent designations were classified as eye irritants.

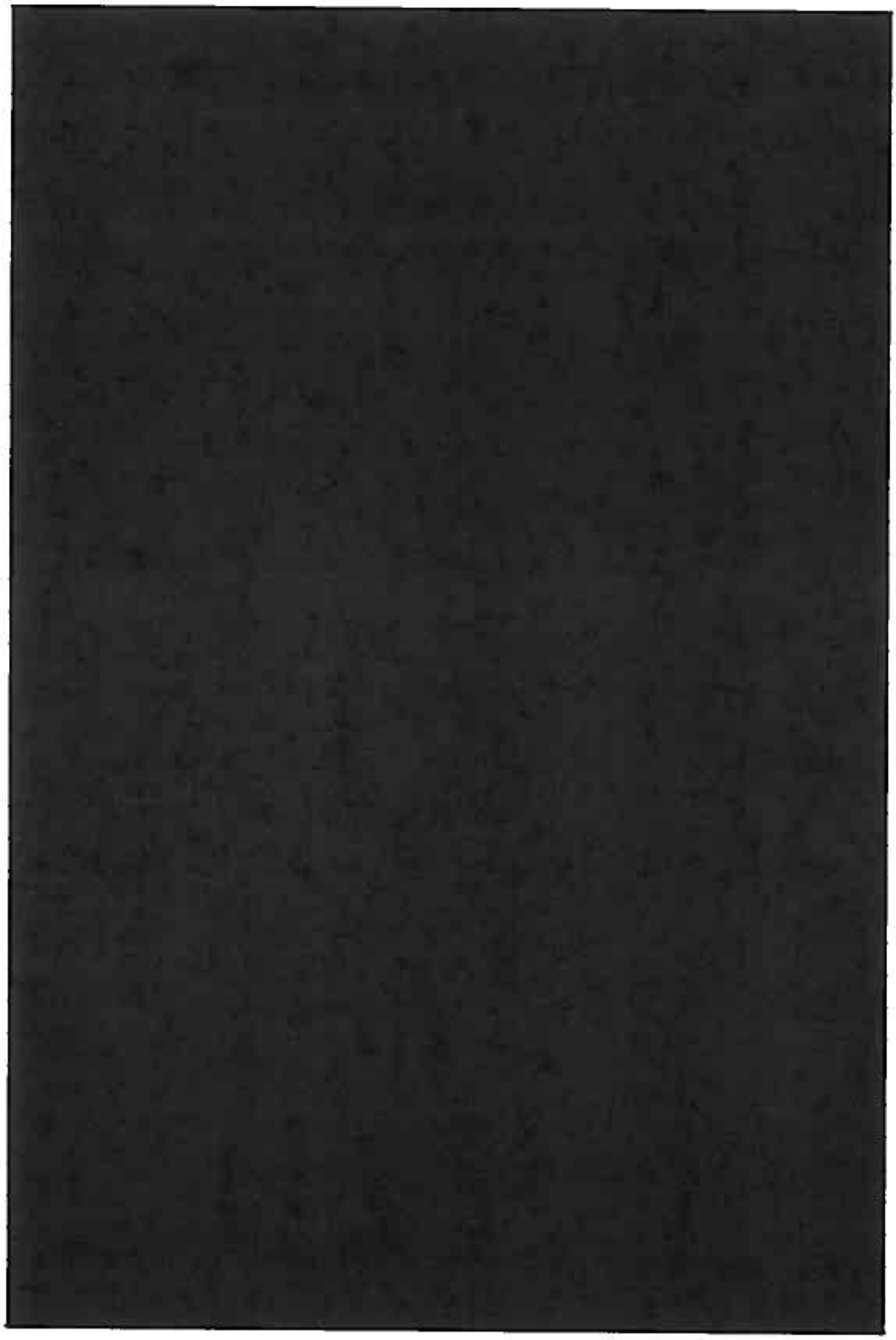
The eye is a mucous membrane. A mucous membrane or mucosa is a membrane that lines various cavities in the body and covers the surface of internal organs. It consists of one or more layers of epithelial cells overlying a layer of loose connective tissue. It is mostly of endodermal origin and is continuous with the skin at various body openings such as the eyes, ears, inside the nose, inside the mouth, lip, vagina, the urethral opening, and the anus. Some mucous membranes secrete mucus, a thick protective fluid. The function of the membrane is to stop pathogens and dirt from entering the body and to prevent bodily tissues from becoming dehydrated.

Of the 141 fragrance chemicals in the product, 58 fragrance chemicals are designated as irritants, 110 are designated as skin irritants and 104 are eye irritants.

A summary of the findings is provided in Table 8 and a comparison of the number of fragrance chemicals designated as irritants, skin irritants and eye irritants are provided in Figure 3, Figure 4, and Figure 5.

Table 8 **Fragrance Chemicals Added to Johnson & Johnson Baby Powder Product Listed as Irritants, Skin Irritants and Eye Irritants**





[redacted]

Figure 3 **Fragrance Chemicals Classified as an Irritant**

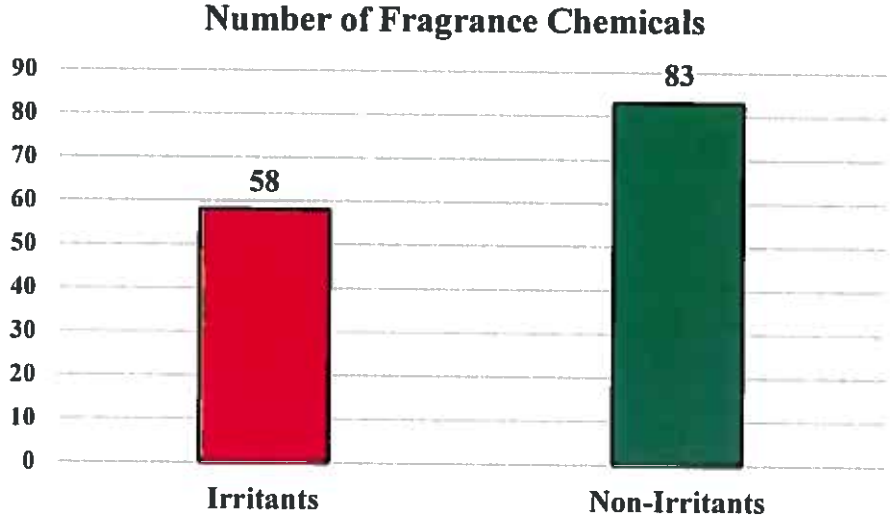


Figure 4 **Fragrance Chemicals Classified as a Skin Irritant**

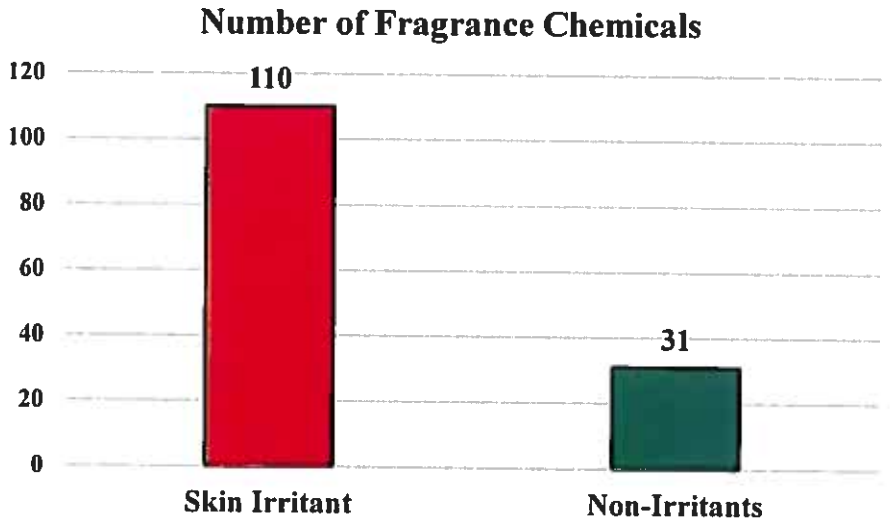
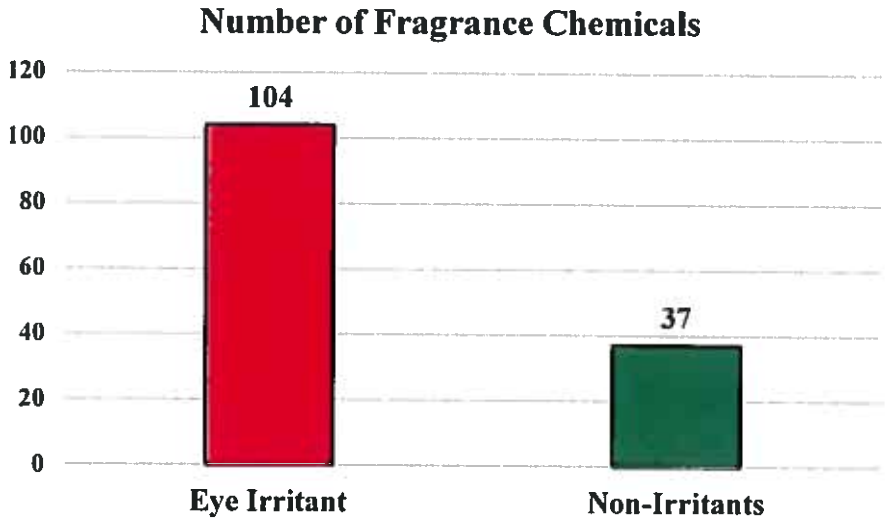


Figure 5 **Fragrance Chemicals Classified as an Eye Irritant**



4.5 Fragrance Chemicals Classified As Sensitizers

Sensitization is an adaptive response in the immune system and or exposure to allergen that results in the development of hypersensitivity. In this sense, sensitization is the term more often in usage for induction of allergic responses or hypersensitivity reaction. It is known that the induction of dermal sensitization is a threshold based phenomenon (Kimber et al., 2008; Robinson et al., 2000).

OSHA defines a sensitizer as "a chemical that causes a substantial proportion of exposed people or animals to develop an allergic reaction in normal tissue after repeated exposure to the chemical." The condition of being sensitized to a chemical is called chemical hypersensitivity.

Because sensitization is an immune response, some people may be easily sensitized while others may never be affected. Once a person is sensitized to a particular chemical, even minute amounts can cause symptoms. Sensitization is usually a life-long effect.

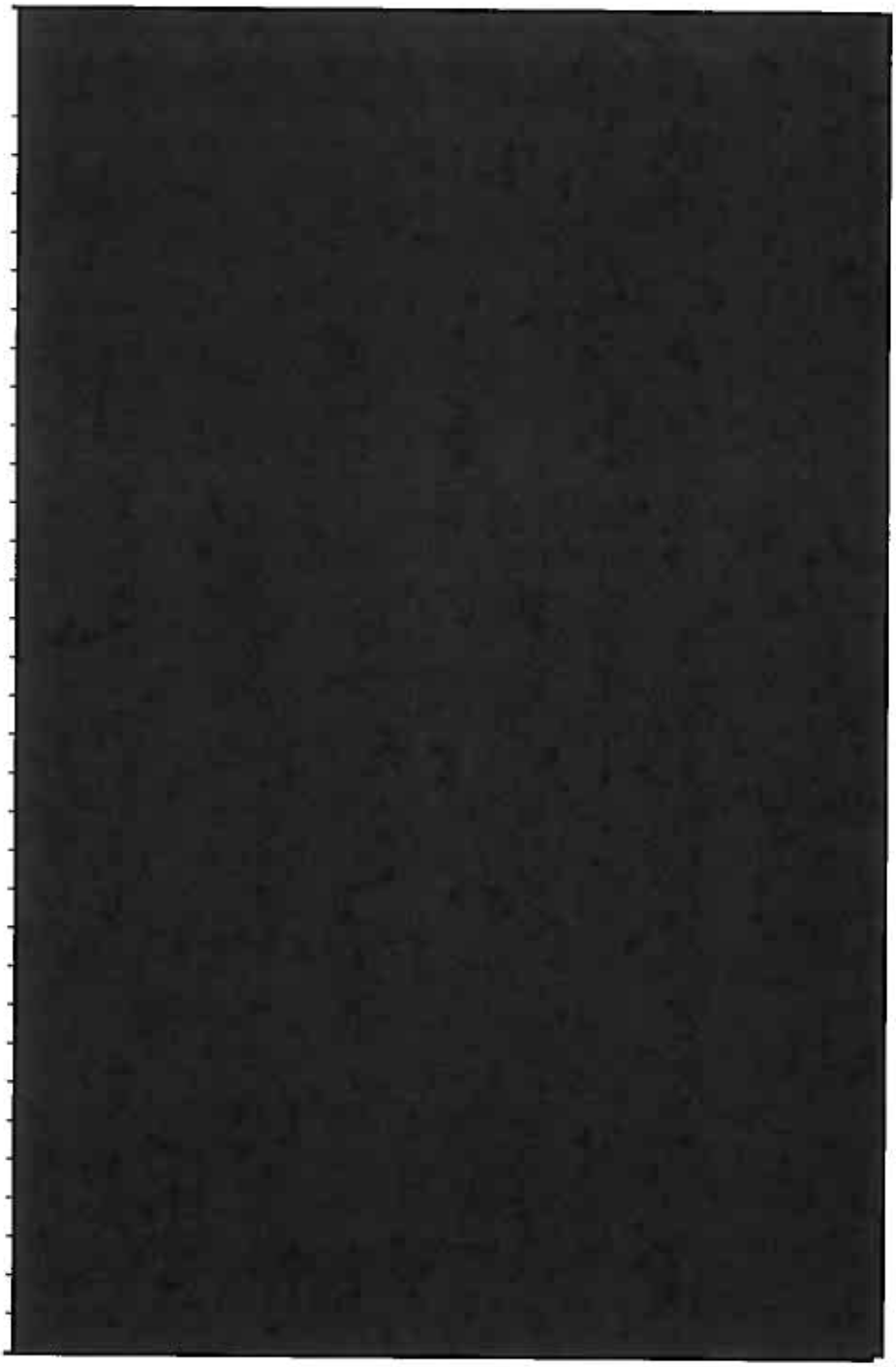
Traditionally, sensitization has been determined using animal testing. On April 10, 2018, the US EPA released a draft Science Policy to reduce the use of animals in testing chemicals to evaluate whether they cause an allergic reaction, inflammation or sensitization of the skin. The draft policy was open for public comment until June 9, 2018. The document is titled Draft Interim Science Policy: Use of Alternative Approaches for Skin Sensitization as a Replacement for Laboratory Animal Testing and describes the science behind the non-animal alternatives that can now be used (in vitro, in silico, in chemico) to identify skin sensitization.

The fragrance chemicals were reviewed to identify those that are classified as sensitizers according to the Globally Harmonized System of Classification and Labelling of Chemicals in accordance with 29 CFR 1910 (OSHA HCS). Fragrance Chemicals with R38, R 42/43, H317 or equivalent designations were classified as sensitizers. In addition, Fragrance Chemicals designated by IFRA as sensitizers were classified accordingly.

Of the 141 fragrance chemicals in the product, 39 fragrance chemicals are classified as sensitizers.

A summary of the findings is provided in Table 9 and a comparison of the number of fragrance chemicals designated as irritants, skin irritants and eye irritants are provided in Figure 6.

Table 9 **Fragrance Chemicals Added to Johnson & Johnson Baby Powder Product with Sensitization Warnings**



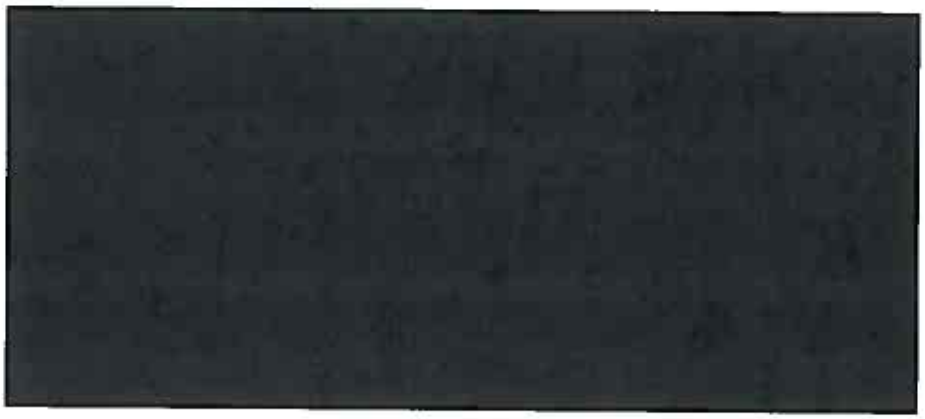
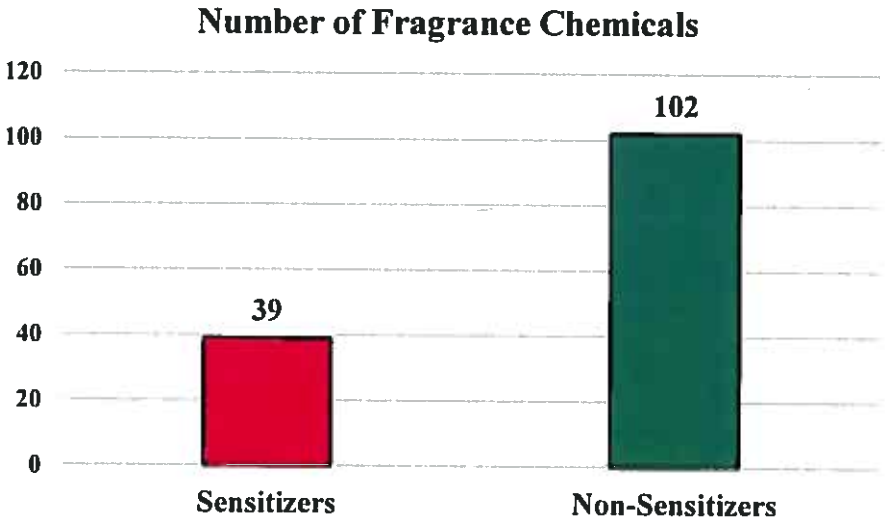


Figure 6 **Number of Fragrance Chemicals Classified as a Sensitization Hazard**



4.6 Fragrance Chemicals Classified As Allergens and or Cause Contact Dermatitis

An allergen is a type of antigen that produces an abnormally vigorous immune response in which the immune system fights off a perceived threat that would otherwise be harmless to the body.

The fragrance chemicals were reviewed to identify those that are classified as allergens according to the Globally Harmonized System of Classification and Labelling of Chemicals in accordance with 29 CFR 1910 (OSHA HCS). Fragrance Chemicals with H317, H334 or equivalent designations were classified as allergens. Fragrance chemicals with literature reports of contact dermatitis were also classified accordingly.

Of the 141 fragrance chemicals in the product, 35 fragrance chemicals are classified as allergens and or cause contact dermatitis.

A summary of the findings is provided in Table 10 and a comparison of the number of fragrance chemicals designated as irritants, skin irritants and eye irritants are provided in Figure 7.

Table 10 **Fragrance Chemicals Added to Johnson & Johnson Baby Powder Product Classified as Allergens and or Can Cause Contact Dermatitis**

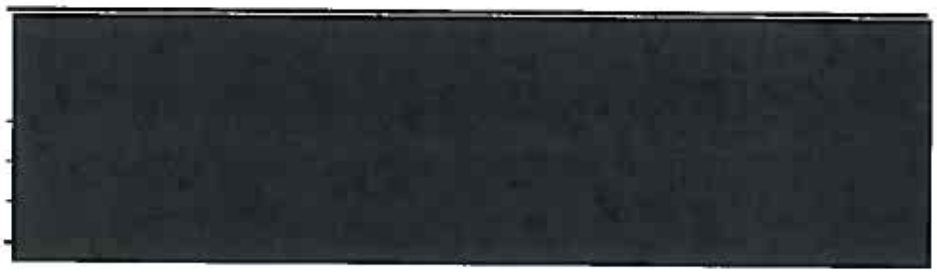
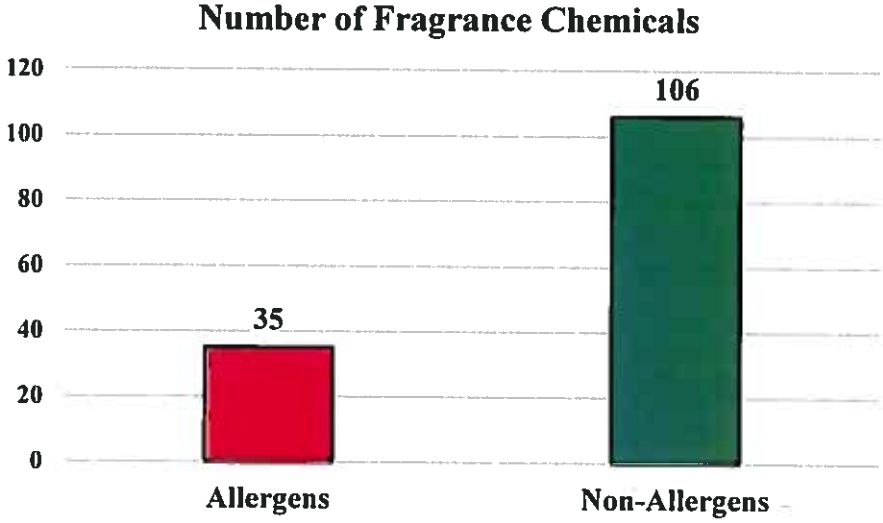


Figure 7 **Fragrance Chemicals Classified as Allergens and or Cause Contact Dermatitis**



4.7 Fragrance Chemicals with IFRA Critical Effects

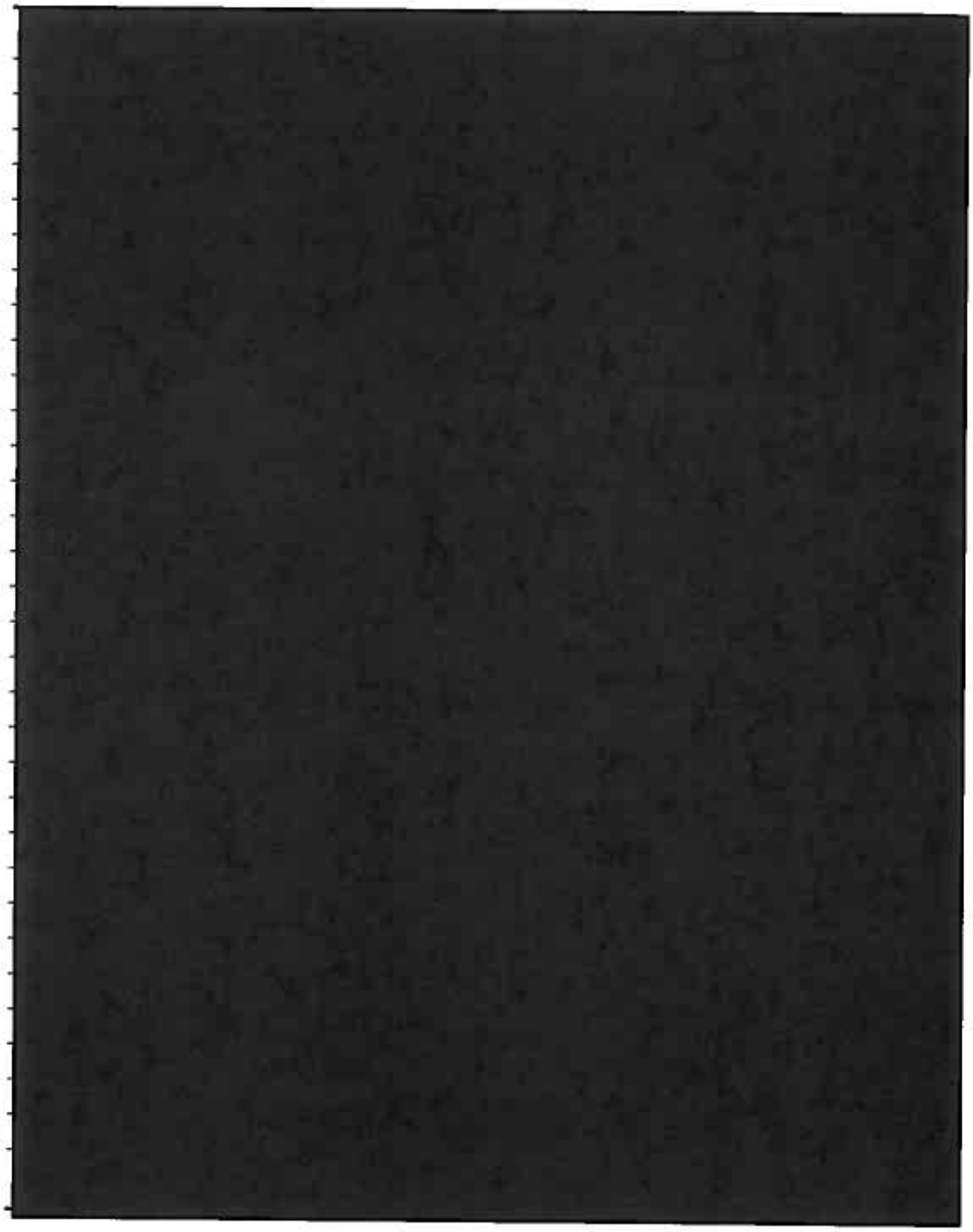
The fragrance industry has maintained a system of safety assurance since 1973. IFRA sets standards that are intended to ensure the safe use of fragrance ingredients for the consumer and the environment. IFRA Standards are based on a scientific assessment of potential hazards (extensive set of toxicological data) and comprehensive information on the use of and exposure to fragrance materials by RIFM and subsequent evaluation by the RIFM expert panel.

RIFM is the scientific institute for the fragrance industry and is responsible for generating, evaluating and distributing scientific data on the safety of fragrance materials in consumer products. The scientific program at RIFM is guided by the RIFM expert panel. RIFM's scientific information is published in peer reviewed journals. The Expert Panel's conclusions include definition of critical effects and a safety evaluation based upon reported use. The process of RIFM risk assessment has been described (David R. Bickers et al., 2003)

The fragrance chemicals were reviewed to identify those that are designated with an IFRA Critical Effect.

Of the 141 fragrance chemicals in the product, 39 fragrance chemicals have an IFRA Critical Effect. A summary of the findings is provided in Table 11 and a comparison of the number of fragrance chemicals designated with an IFRA Critical Effect is provided in Figure 8.

Table 11 Fragrance Chemicals Added to Johnson & Johnson Baby Powder Product with IFRA Critical Effects



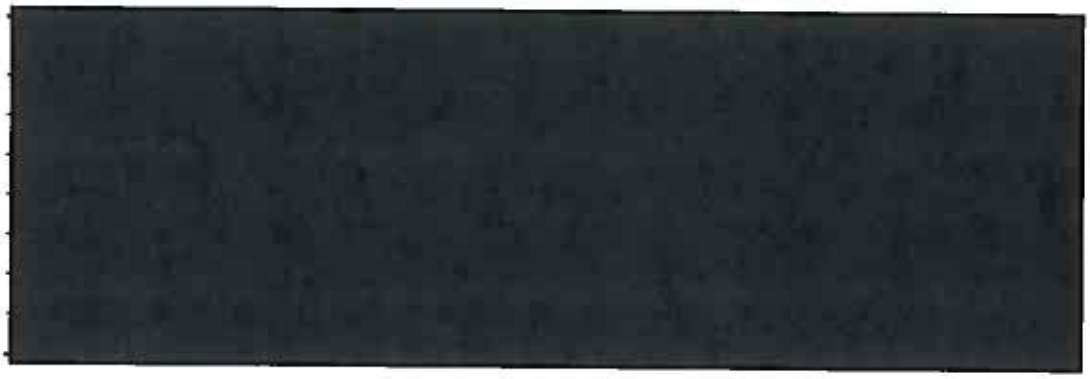
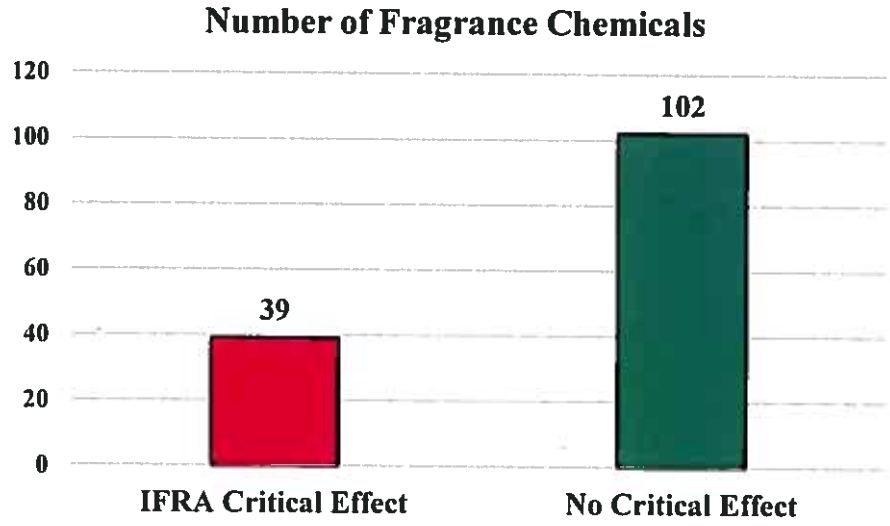


Figure 8 **Fragrance Chemicals with IFRA Critical Effects**



4.8 Fragrance Chemicals with IFRA Category 5 Restrictions

IFRA & RIFM developed the Quantitative Risk Assessment (QRA) to determine safe use levels of fragrance ingredients in a variety of consumer product types (Api & Vey, 2008b; IFRA & RIFM, 2015; McNamee et al., 2008; Politano & Api, 2008). The QRA specifically addresses the elements of exposure-based risk assessment that are unique to the induction of dermal sensitization, while being consistent with the principles of general toxicology risk assessment. The QRA is an improvement over the risk management strategies formerly used by IFRA, in which each specific fragrance ingredient identified as an allergen was limited to the same concentration across all skin contact product types (Api et al., 2008).

IFRA has "capped" the usage levels on certain fragrances due to dermal sensitization and allergic response concerns (Cowan-Ellsberry, McNamee, & Leazer, 2008; Kimber et al., 2008). The restrictions are retrospective, based on old methodology, and prospective, based upon the QRA system (Api & Vey, 2008a). Standards that impose a quantitative limit on the use of fragrance materials are expressed as a maximum concentration of fragrance material in the consumer product. This implies knowledge of the

concentration of the restricted fragrance material in the compound and the concentration of the compound in the final consumer product. Fragrance suppliers are therefore required to inform manufacturers of consumer products, who use or intend to use a fragrance compound, that due to the presence of a restricted ingredient, the compound should only be used up to a specified maximum concentration or in well-defined applications, thereby being in compliance with IFRA Standards. Unless otherwise specified, concentrations are expressed in weight-weight percent.

From the 40th Amendment on, the Standards limiting ingredients due to sensitization are based on the Quantitative Risk Assessment for dermal sensitizers (QRA). The QRA methodology for fragrance ingredients is a refined risk assessment approach for dermal sensitizers, which currently identifies individual limitations for 11 specific product categories (based on similar Safety Assessment Factors and exposure).

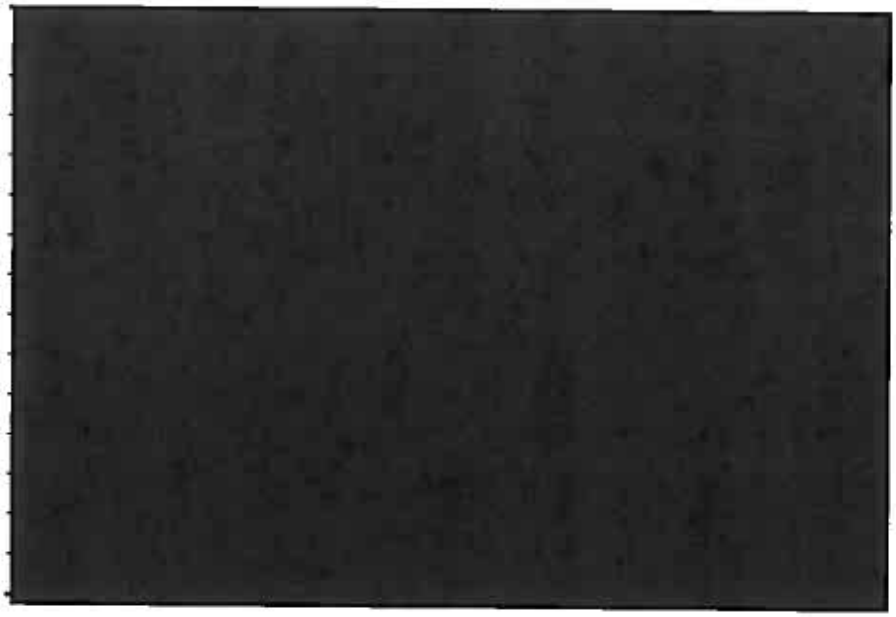
"Baby Powder and Talcs" have been assigned to Category 5. Category 5 also includes Women's Facial Creams/Facial Make-up, Hand Cream, Facial Masks, Hair Permanent and other hair chemical treatments (e.g. relaxers) but not hair dyes, Wipes or Refreshing Tissues for Face, Neck, Hands, Body, Hand Sanitizers and Dry Shampoo or Waterless Shampoo.

The fragrance chemicals were reviewed to identify those that are designated with a Category 5 Restriction.

Of the 141 fragrance chemicals in the product, 23 fragrance chemicals have a Category 5 Restriction. A summary of the findings is provided in Table 12 and a comparison of the number of fragrance chemicals designated with a Category 5 Restriction is provided in Figure 9.

An example of how the QRA examines fragrance ingredients was published on Citral, one of the fragrance ingredients in the Baby Powder product (Jon Lalko & Api, 2008).

Table 12 Fragrance Chemicals Added to Johnson & Johnson Baby Powder Product with IFRA Category 5 Restriction



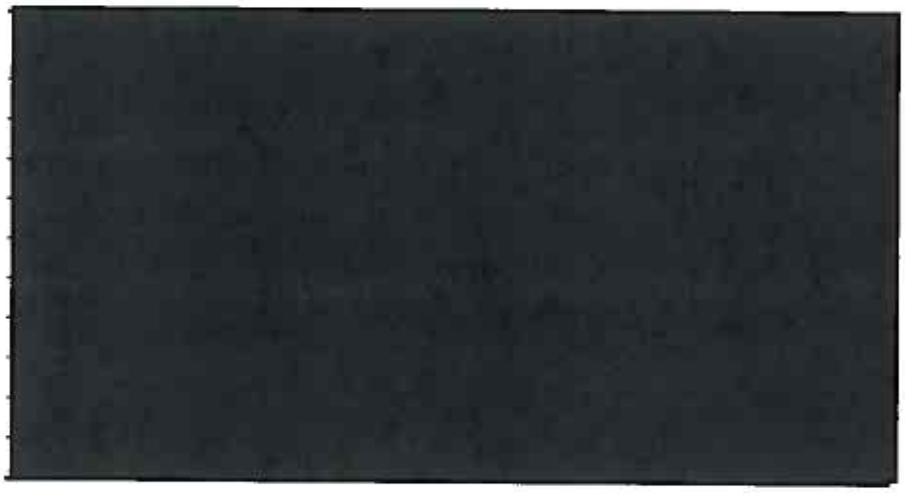
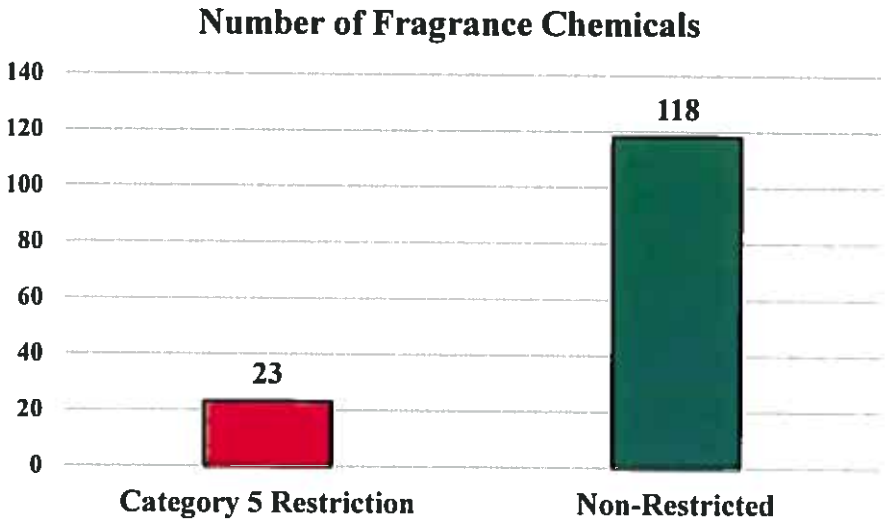


Figure 9 **Fragrance Chemicals with a Category 5 Restriction**



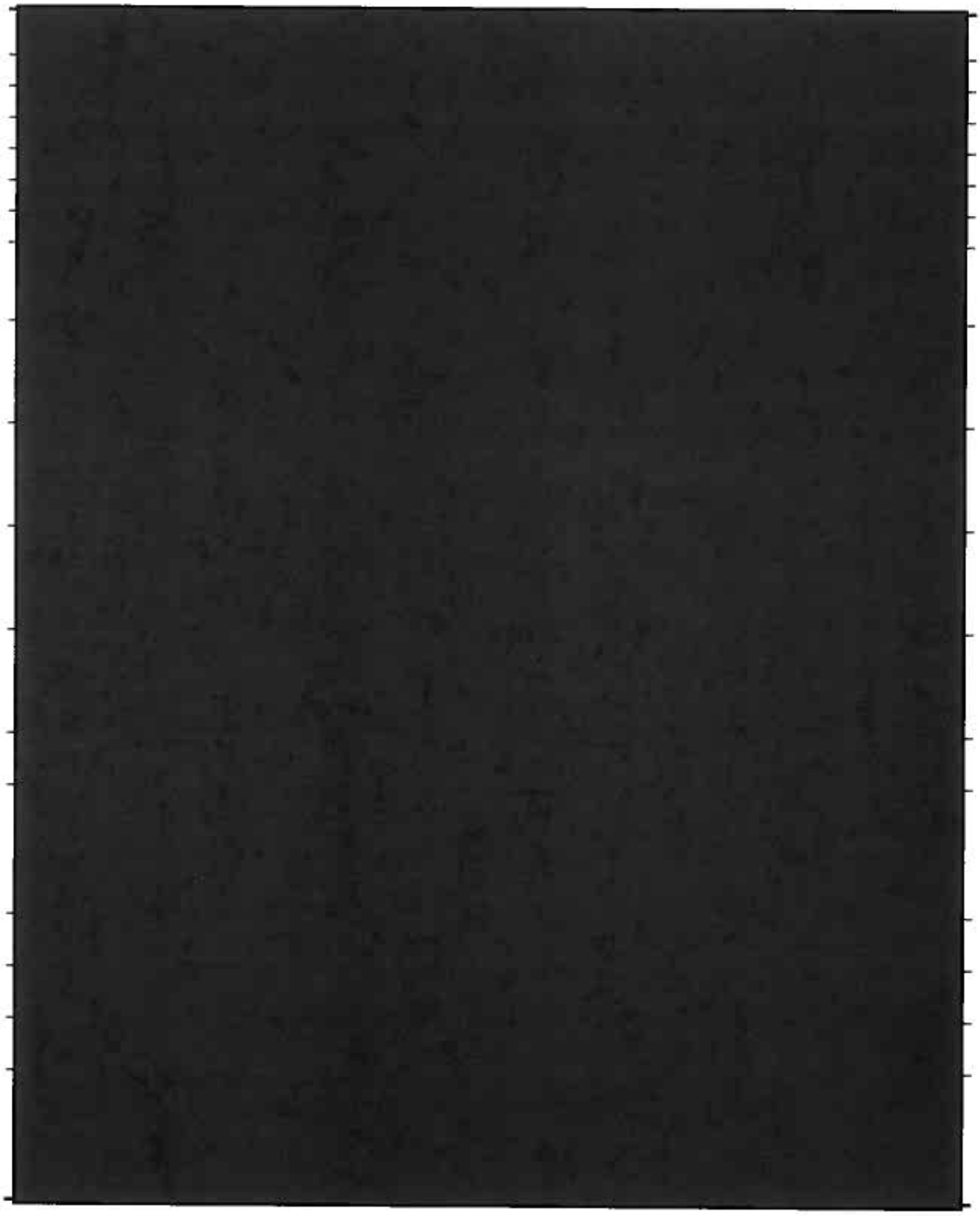
4.9 Fragrance Chemicals with Exposure Limits

Prior to the QRA, IFRA & RIFM established exposure limits. Exposure limits for these chemicals were established to reduce the risk of dermal sensitization and as such, are not related to considerations of safe levels for ingestion. These limits remain as part of an IFRA standard if a specific fragrance has not been through the QRA process.

The fragrance chemicals were reviewed to identify those that are designated with Exposure Limits.

Of the 141 fragrance chemicals in the product, 25 fragrance chemicals have an Exposure Limit. A summary of the findings is provided in Table 13 and a comparison of the number of fragrance chemicals designated with an Exposure Limit is provided in Figure 10.

Table 13 **Fragrance Chemicals Added to Johnson & Johnson Baby Powder Product with Exposure Limits**



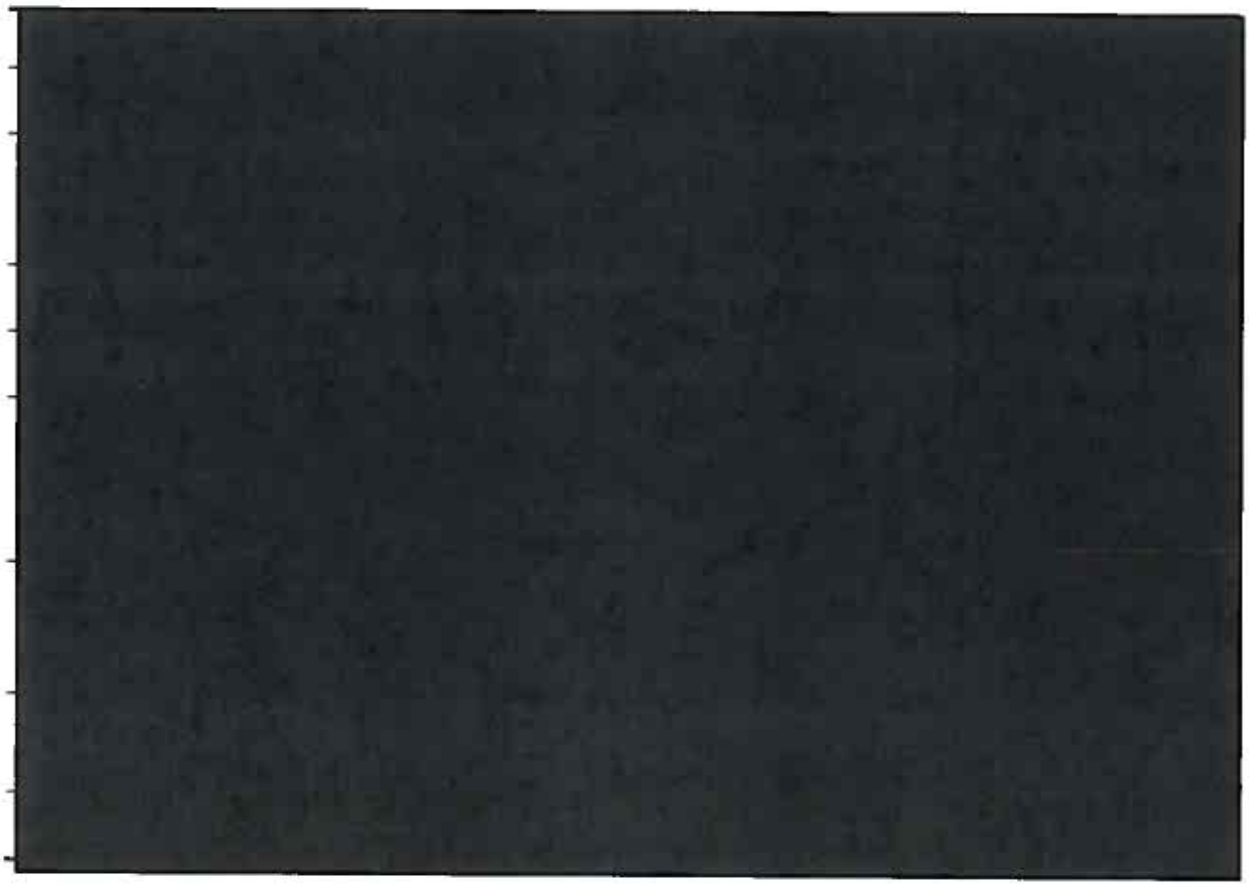
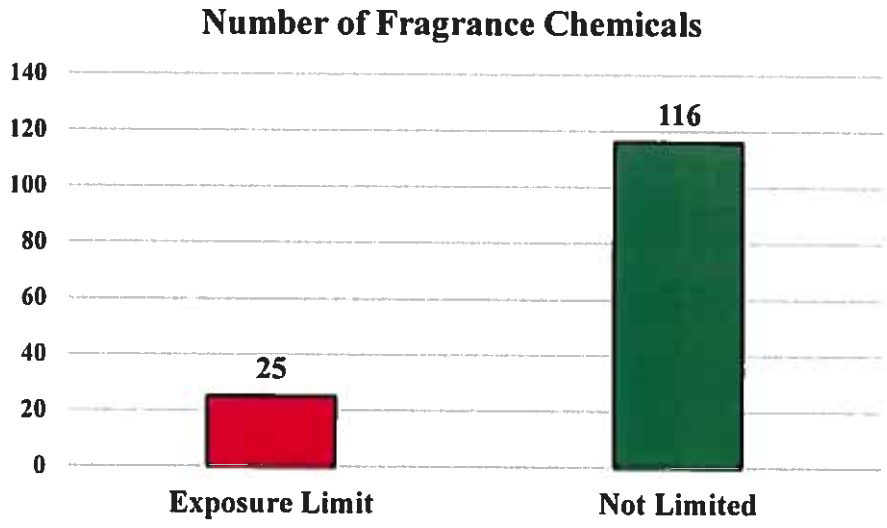


Figure 10 **Fragrance Chemicals with an Exposure Limit**



4.10 Fragrance Chemicals Listed on the FDA Inactive Ingredient Database (IID)

The US Food and Drug Administration maintains the Inactive Ingredient Database (IID). The Inactive Ingredient Database provides information on inactive ingredients present in FDA-approved drug products. In general, inactive ingredients on this list have been subject to extensive toxicology studies for a given route of administration.

When a new drug product is submitted to the FDA, the agency reviews the inactive ingredients used in that drug product. FDA considers the amount of each inactive ingredient, the route of administration (i.e. oral, injection, transdermal, otic, vaginal, ophthalmic), and whether the inactive ingredients have demonstrated safety for each specific route. If an inactive ingredient has not previously been approved for the route of administration, FDA requests that the sponsor demonstrate safety.

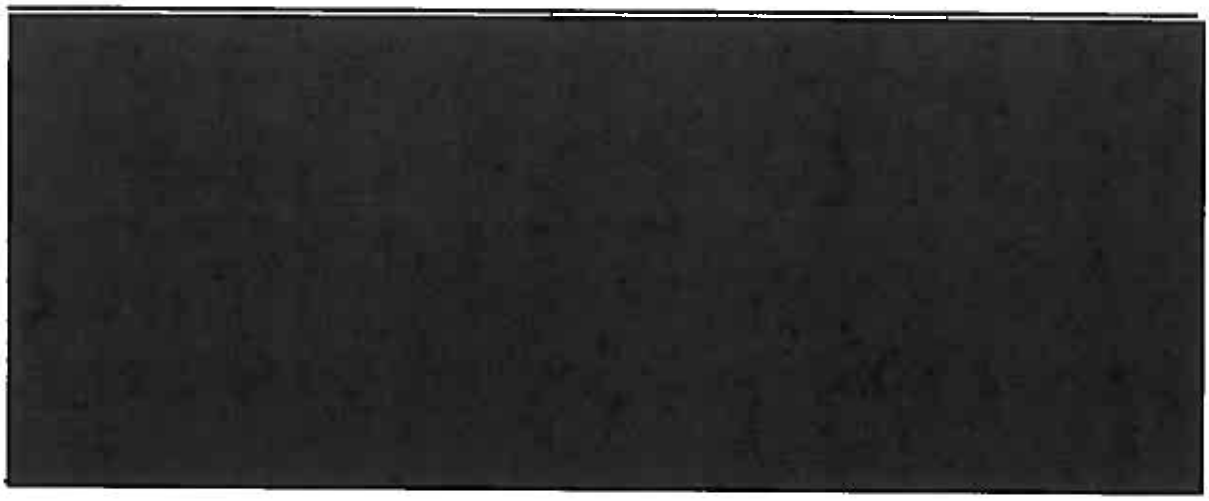
The fragrance chemicals were reviewed to identify those listed on the FDA IID, including those listed for topical administration (applied to the skin) and vaginal administration.

Of the 141 fragrance chemicals in the product, 26 fragrance chemicals are listed on the FDA IID, 9 are present in an approved drug products for topical administration and 1 is present in an approved drug product for vaginal administration.

FDA and EFSA consider oral administration for flavors. IFRA and CIR consider topical administration (i.e. application to the skin) for fragrances and cosmetic ingredients. In this matter, the talcum products were applied to the perineal area. An unintended consequence of perineal application of the talcum products would be transport into the vaginal cavity and exposure to the vagina, endometrium, fallopian tubes and ovaries. The safety margins of 140 of the fragrance chemicals were determined for foods (oral administration) or cosmetics (topical application to the skin), except for the 1 fragrance chemical on the FDA IID in an approved drug product administered to the vagina.

A summary of the findings is provided in Table 14 and a comparison of the number of fragrance chemicals on the FDA IID in Figure 11, on the IID for topical administration in Figure 12 and on the IID for vaginal administration in Figure 13.

Table 14 Fragrance Chemicals Added to Johnson & Johnson Baby Powder Product Listed on the FDA IID



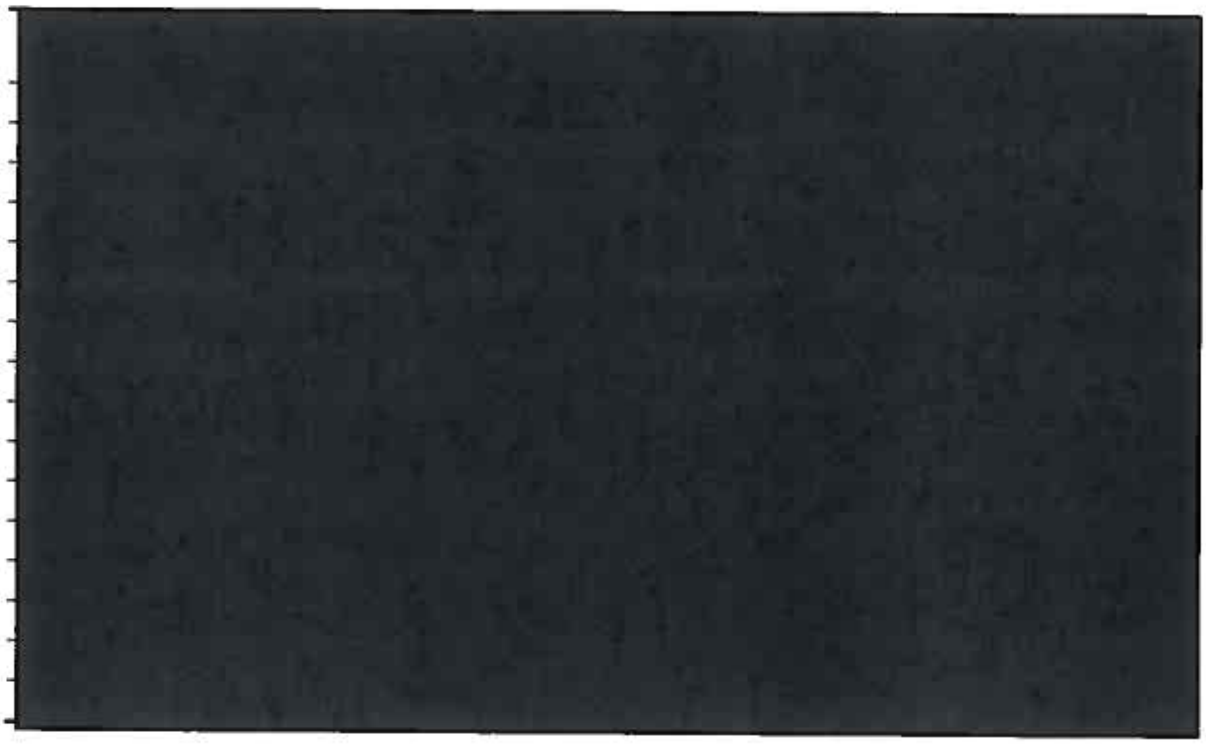


Figure 11 **Fragrance Chemicals Listed on the FDA IID**

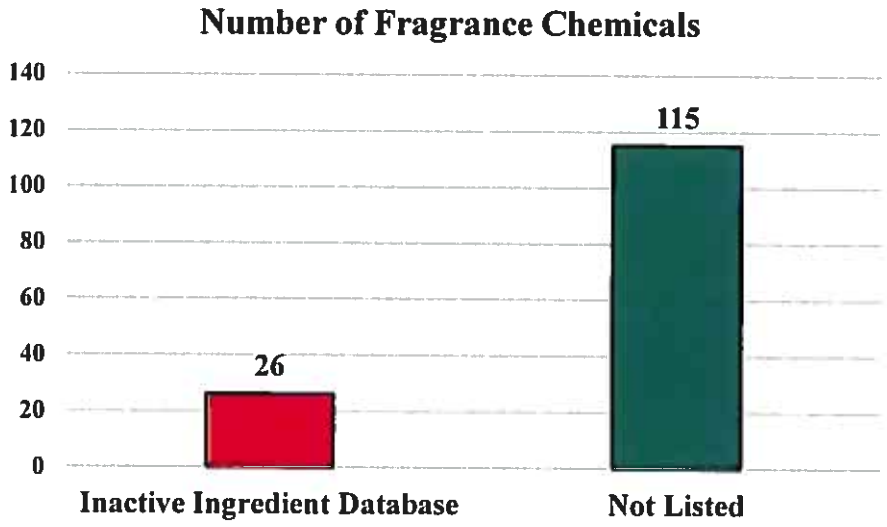


Figure 12 **Fragrance Chemicals Listed on the FDA IID for Topical Administration**

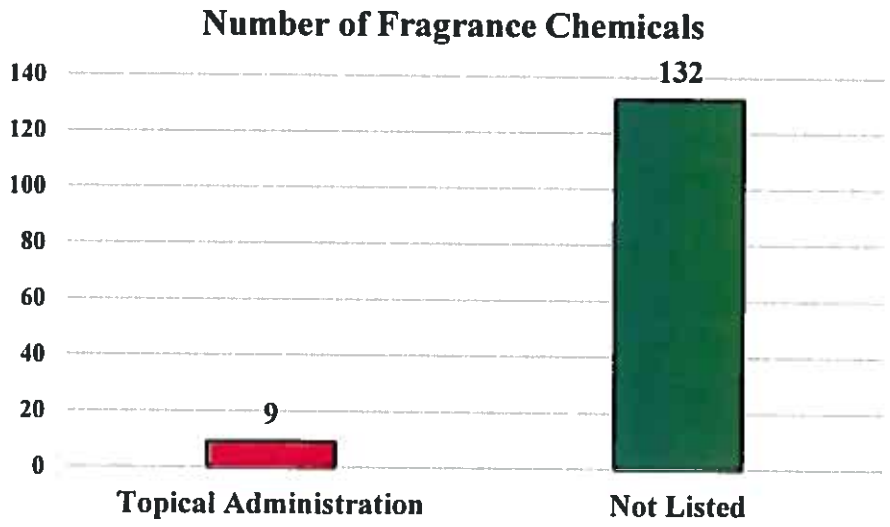
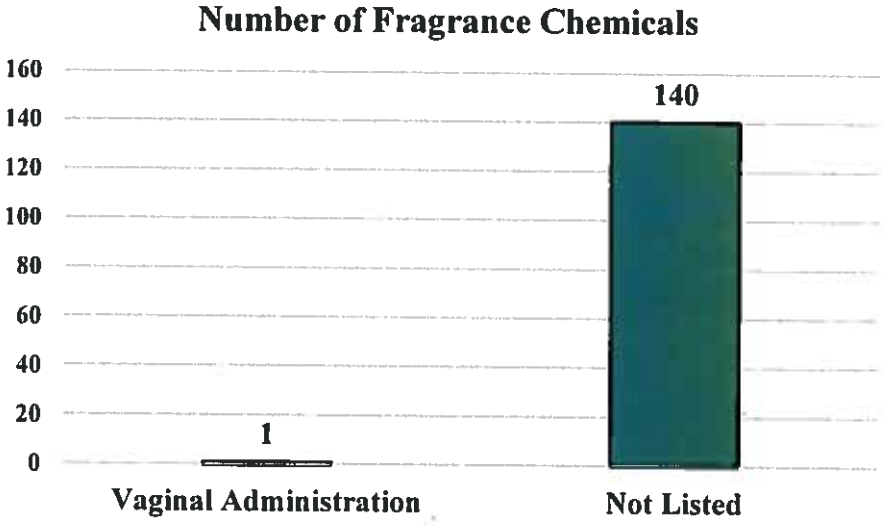


Figure 13 **Fragrance Chemicals Listed on the FDA IID for Vaginal Administration**



5 FRAGRANCE CHEMICALS IN JOHNSON & JOHNSON SHOWER TO SHOWER PRODUCT

The Johnson & Johnson Shower to Shower product contains 53 fragrance chemicals. Some of these fragrances are themselves a mixture of chemicals.

5.1 Unidentified Fragrance Chemicals

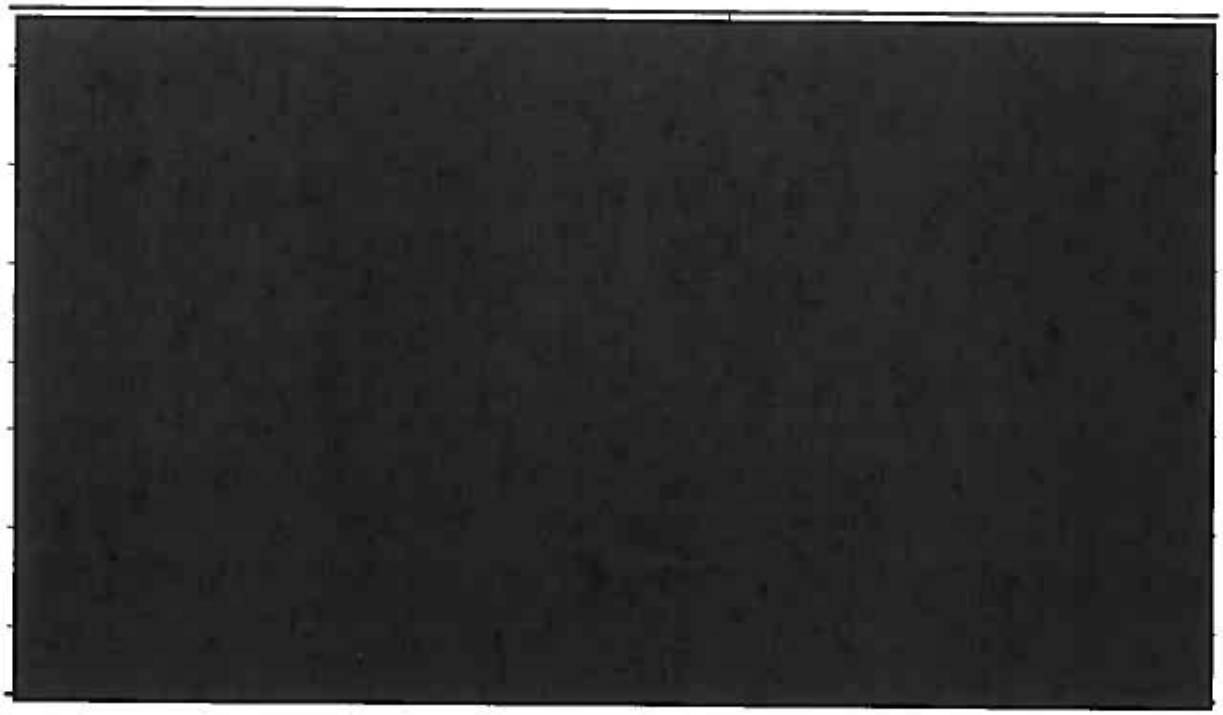
One fragrance chemicals could not be identified: Indisan (Sandela) reaction product.

5.2 Fragrance Chemical Regulatory Review

As described in Section 4.2, a regulatory review of the fragrance chemicals was performed. Eighteen (18) fragrance chemicals in the Johnson & Johnson Shower to Shower product were identified that are either (1) not listed in Title 21 of the Code of Federal Regulations, (2) not approved for fragrance of flavor use, (3) not permitted for cosmetic use, (4) requires warnings, (5) are not permitted for use on the body, (6) absence of an IFRA Standard and or (7) absence of a CIR listing, or a CIR listing as unsafe or insufficient data to support safety.

A summary of the fragrance chemicals with regulatory concerns is provided in Table 15. A comparison of the number of fragrance chemicals with regulatory concerns to the total number of fragrance chemicals is provided in Figure 14.

Table 15 Fragrance Chemicals Added to Johnson & Johnson Shower to Shower Product with Regulatory Concerns



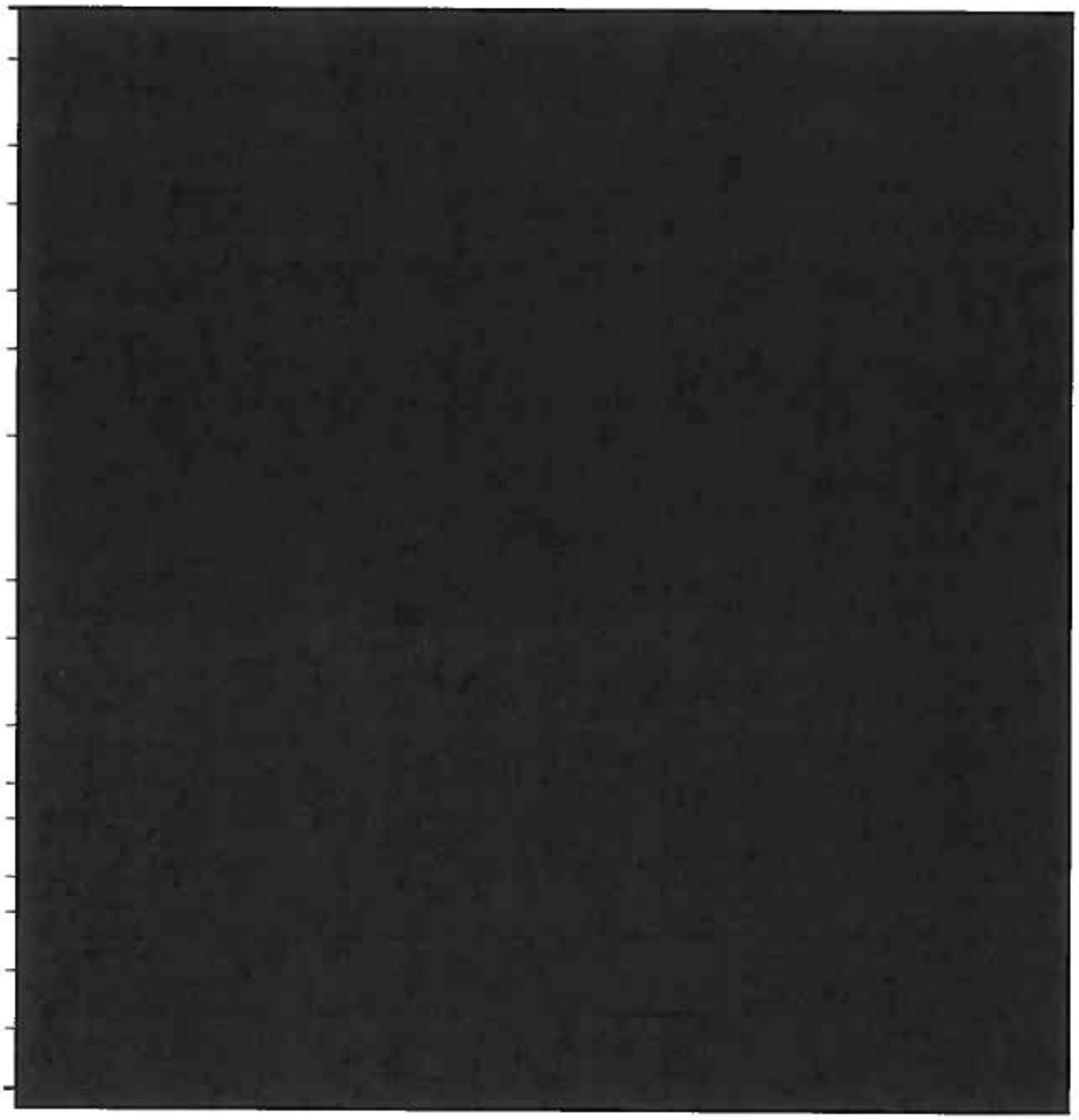
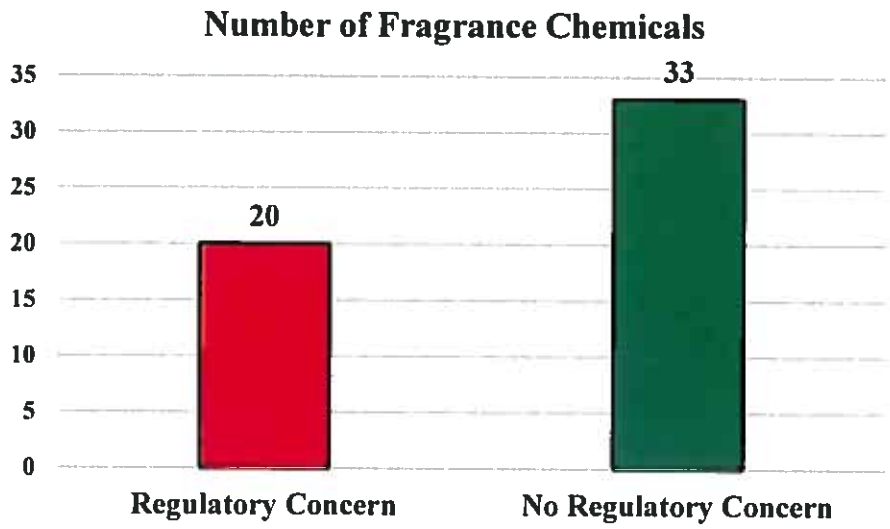


Figure 14 Fragrance Chemicals with Regulatory Concerns



5.3 Fragrance Chemical Safety and Toxicology Review

As described in Section 4.3, the fragrance chemicals in Shower to Shower were reviewed for safety and toxicology. Thirteen (13) fragrance chemicals were found to be listed on the RTECS list (Registry of Toxic Effects of Chemical Substances) or had safety in use concerns.

Three fragrance chemicals added to J&J's Shower to Shower talcum product are included in the IARC monographs as possible carcinogens. Benzophenone has been classified by IARC as a Group 2B possible human carcinogen (International Agency for Research on Cancer (IARC), 2013b). Coumarin and eugenol are "not classifiable" as to their carcinogenicity (Group 3). In addition, Musk ketone is suspected of being a carcinogen, and has been classified as a Category 3 carcinogen by the Scientific Committee on Health and Environmental Risks (SCHER) in Europe. The remainder of the fragrance chemicals in the Shower to Shower product have not been evaluated by IARC as to their carcinogenicity.

Diethyl Phthalate, a non-fragrance present as a component in the fragrance mixture, is a phthalate ester which are reported to be endocrine disruptors, cause reproductive and developmental toxicities, and potentially genotoxic (Al-Saleh, Al-Rajudi, Al-Qudaihi, & Manogaran, 2017).

Benzophenone was recently removed from use in foods by FDA (U.S. Food and Drug Administration, 2018) due to histiocytic sarcoma observed in ovaries and uterus, higher incidences of kidney tumors and leukemia in animal studies (National Toxicology Program (NTP), 2006), and in vivo estrogenic activity (International Agency for Research on Cancer (IARC), 2013a).

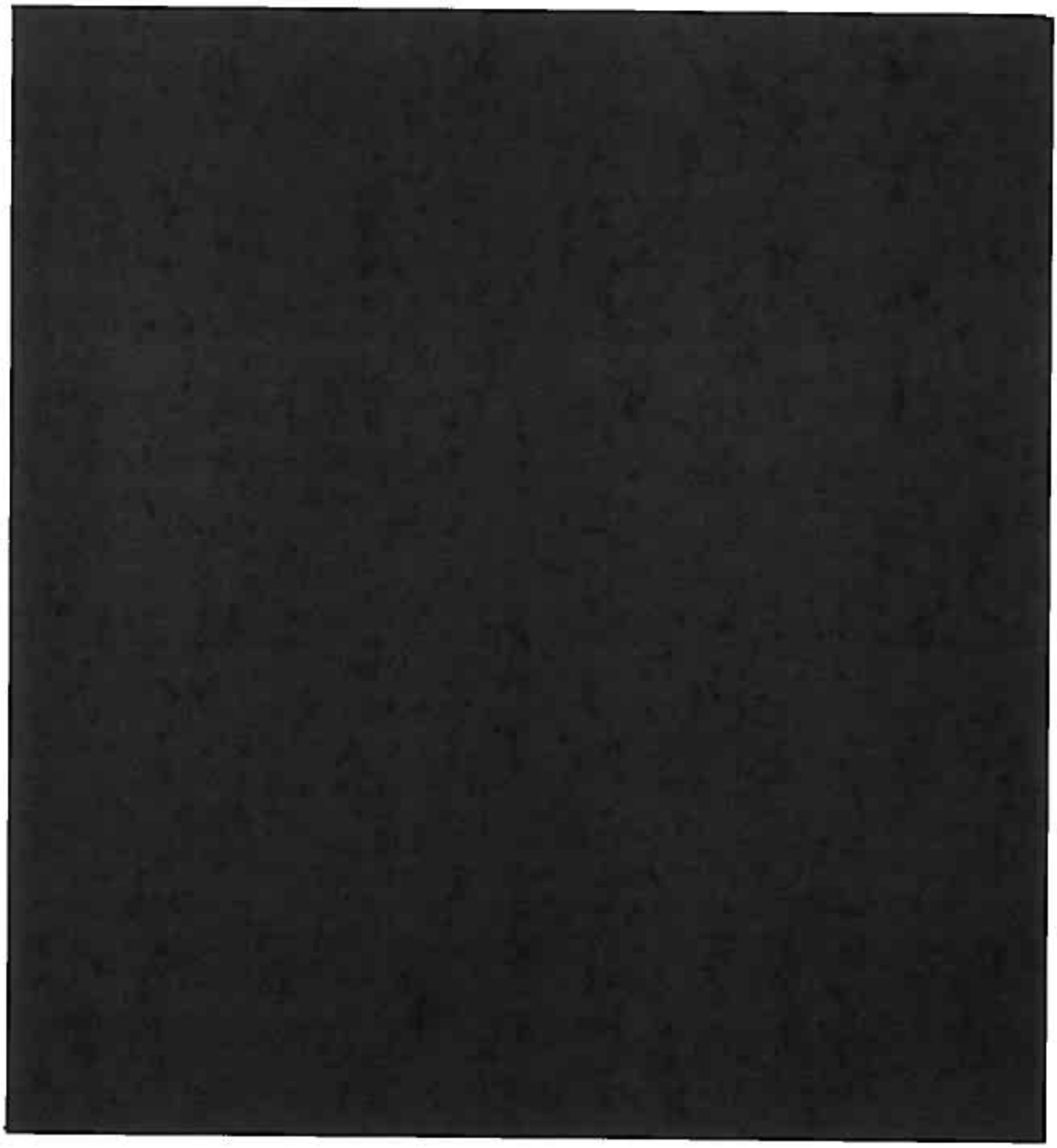
Similarly, equivocal evidence of carcinogenic activity of Diethyl Phthalate in male and female B6C3F1 mice based on increased incidences of hepatocellular neoplasms, primarily adenomas, has been reported (National Toxicology Program (NTP), 1995).

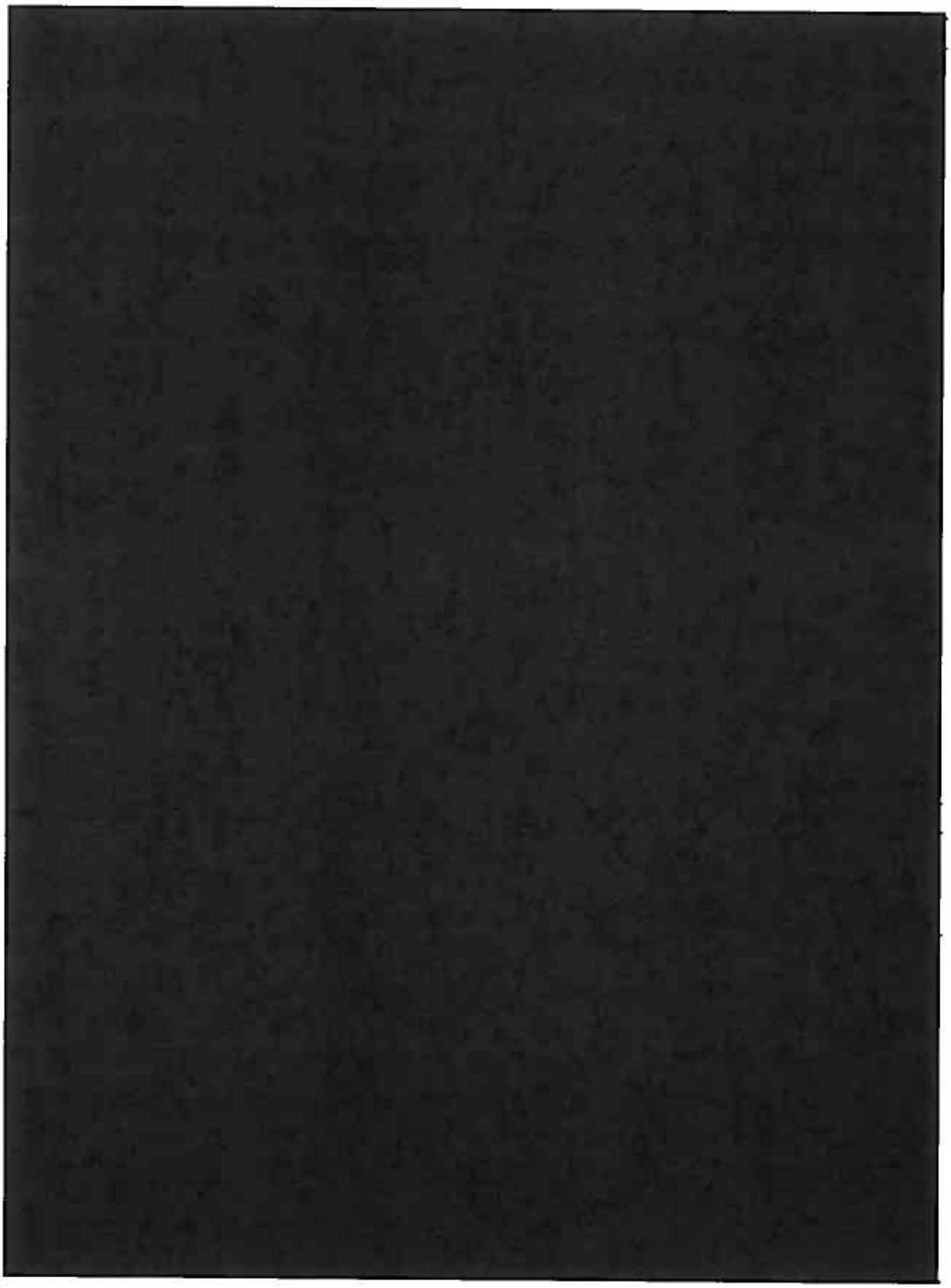
Several chemicals in the fragrance mixture used in the J&J talcum products were identified with in vitro and in vivo studies published in peer reviewed journals demonstrating carcinogenicity, developmental or

reproductive toxicity, genotoxicity, and/or mutagenicity. While these studies are not definitive that the same effects would be observed in humans, they are indicators of biological activity.

A summary of the findings is provided in Table 16 and a comparison of the number of fragrance chemicals with safety and toxicology concerns to the total number of fragrance chemicals in the product is provided in Figure 15.

Table 16 Fragrance Chemicals Added to Johnson & Johnson Shower to Shower Product on the RTECS List and or Toxicity Concerns





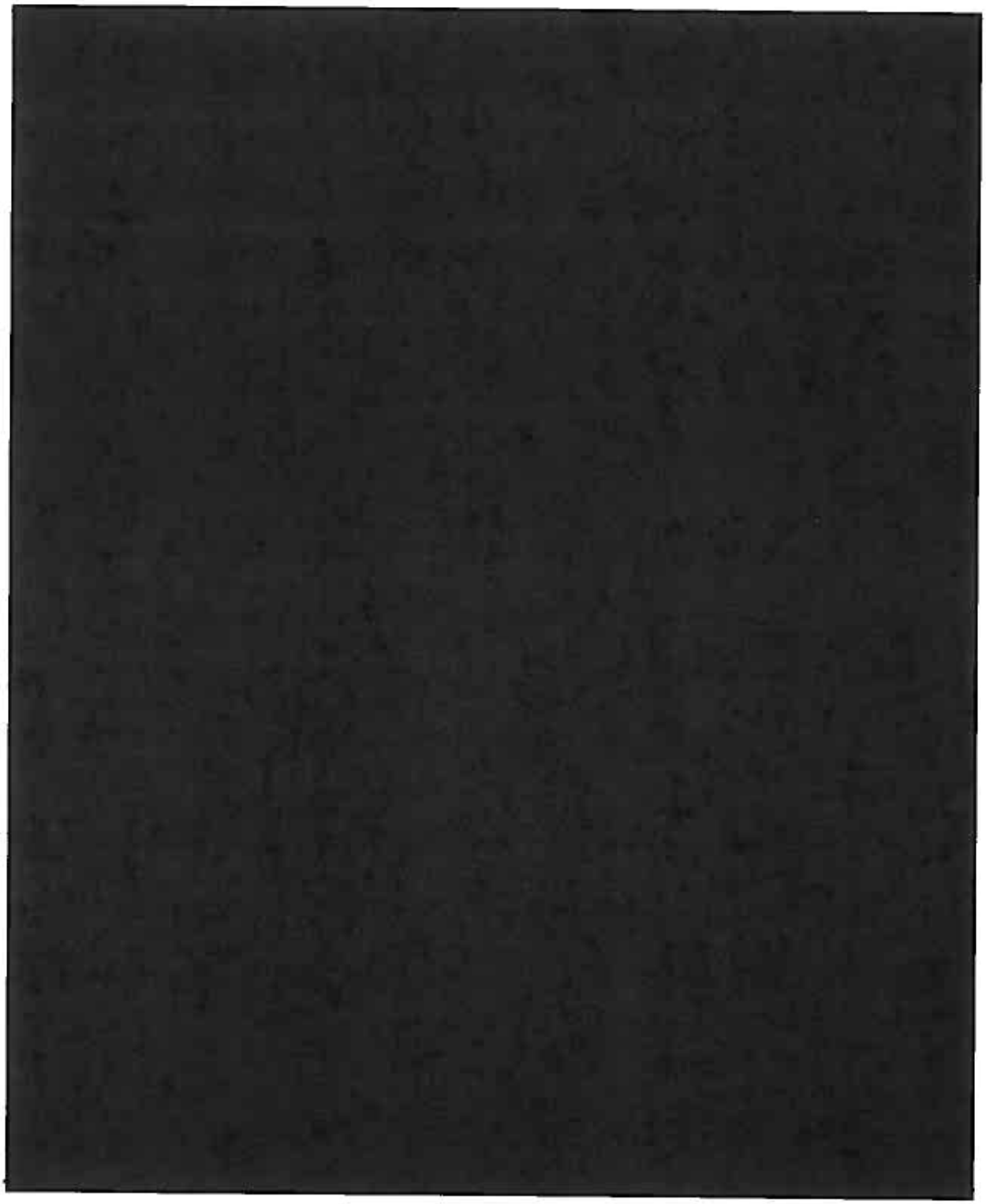
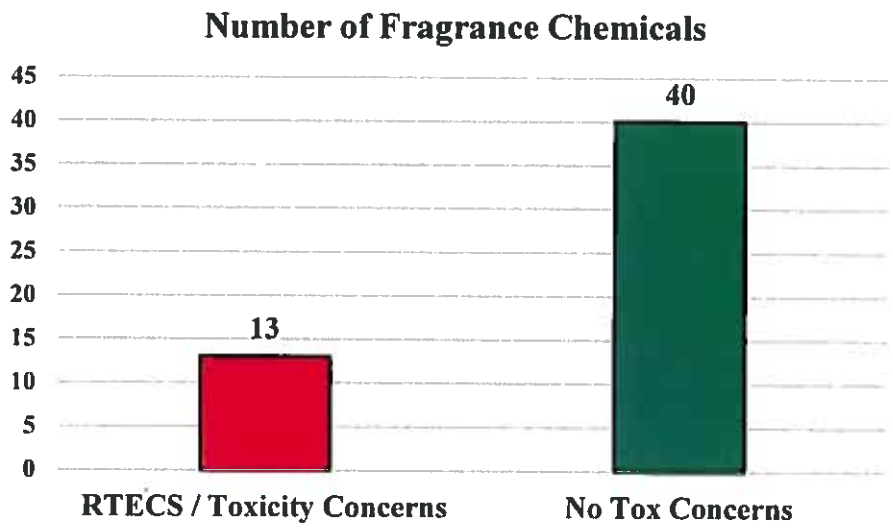


Figure 15 Fragrance Chemicals with Toxicity Concerns



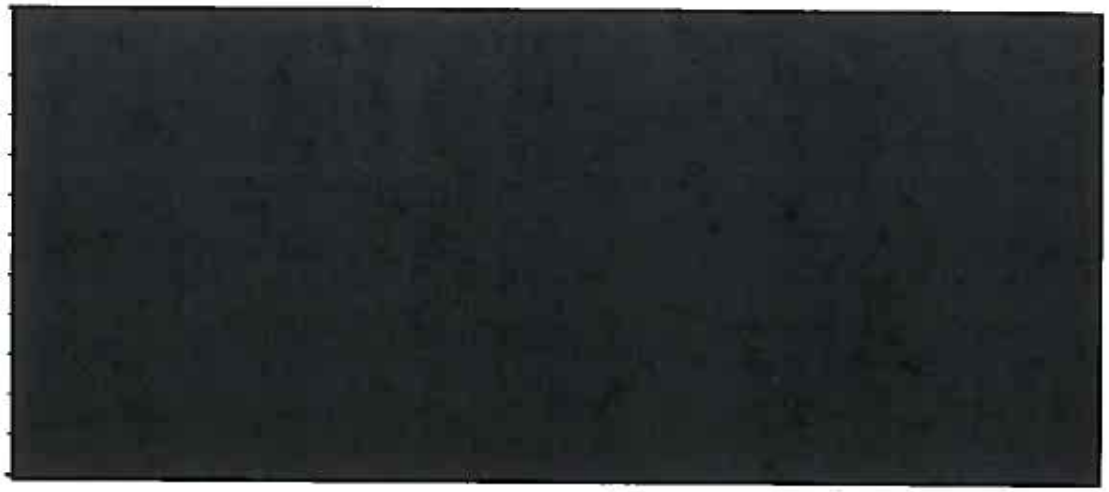
5.4 Fragrance Chemicals Classified As Irritants

As described in Section 4.3, the fragrance chemicals in the Shower to Shower product were reviewed for classification as an irritant.

Of the 53 fragrance chemicals in the product, 25 fragrance chemicals are designated as irritants, 44 are designated as skin irritants and 40 are eye irritants.

A summary of the findings is provided in Table 17 and a comparison of the number of fragrance chemicals designated as irritants, skin irritants and eye irritants are provided in Figure 16, Figure 17 and Figure 18.

Table 17 Fragrance Chemicals Added to Johnson & Johnson Shower to Shower Product Listed as Irritants, Skin Irritants and Eye Irritants



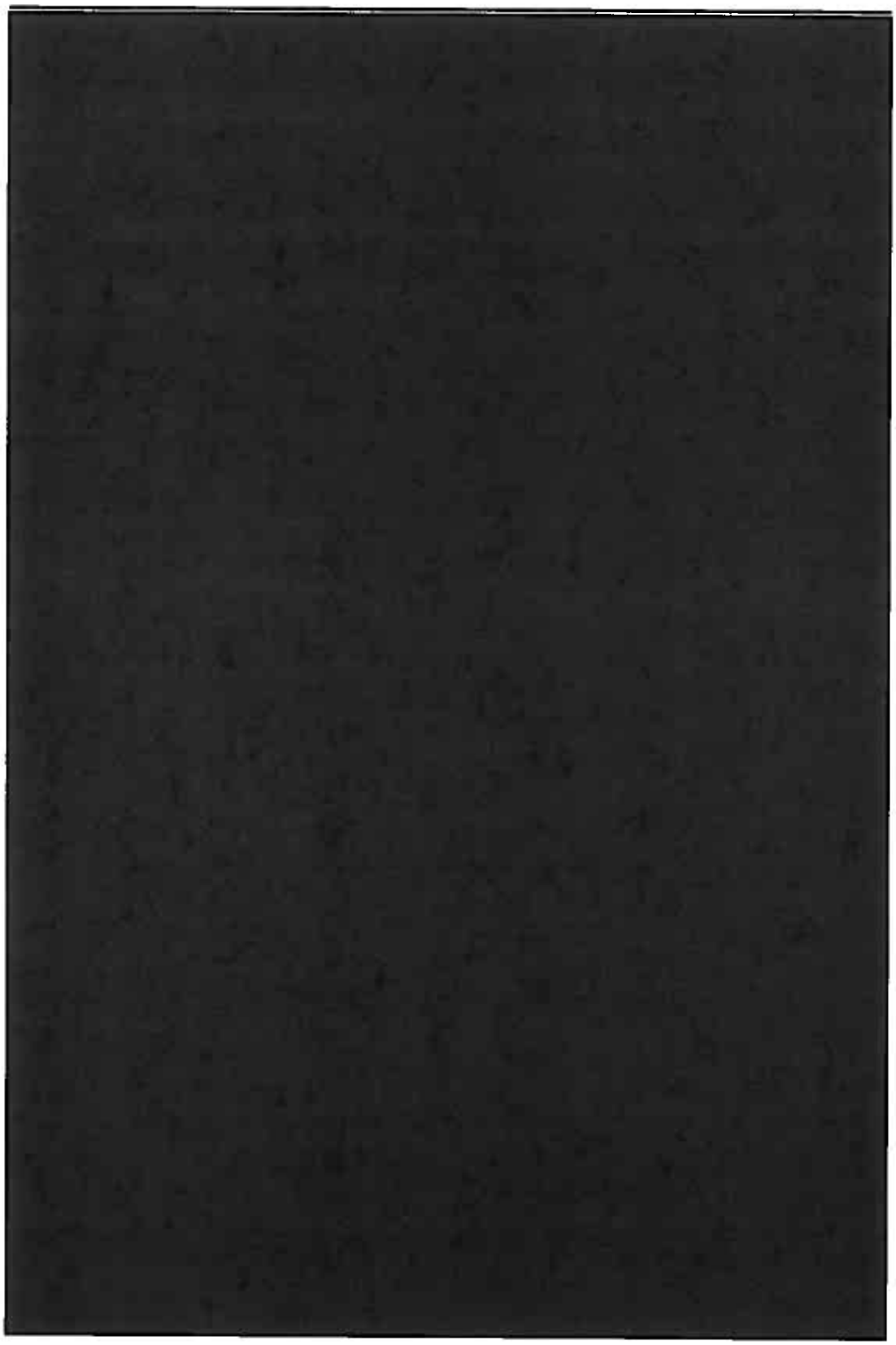


Figure 16 **Fragrance Chemicals Classified as an Irritant**

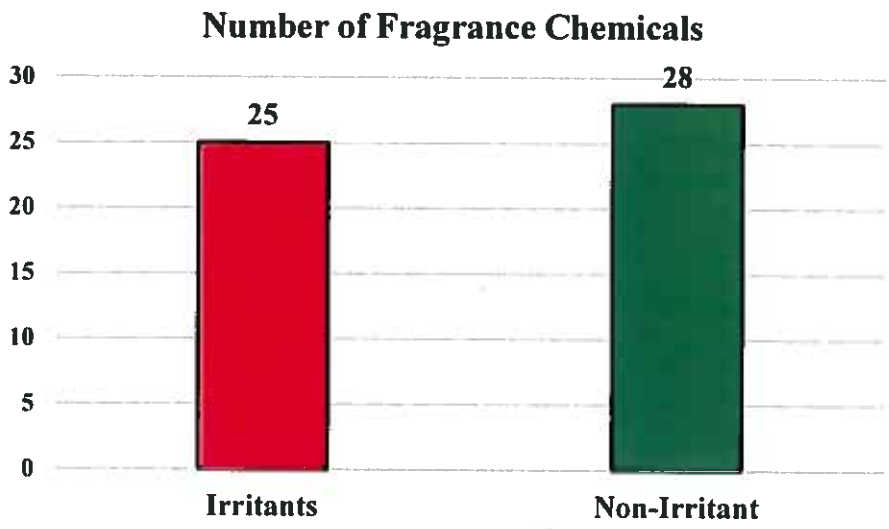


Figure 17 **Fragrance Chemicals Classified as a Skin Irritant**

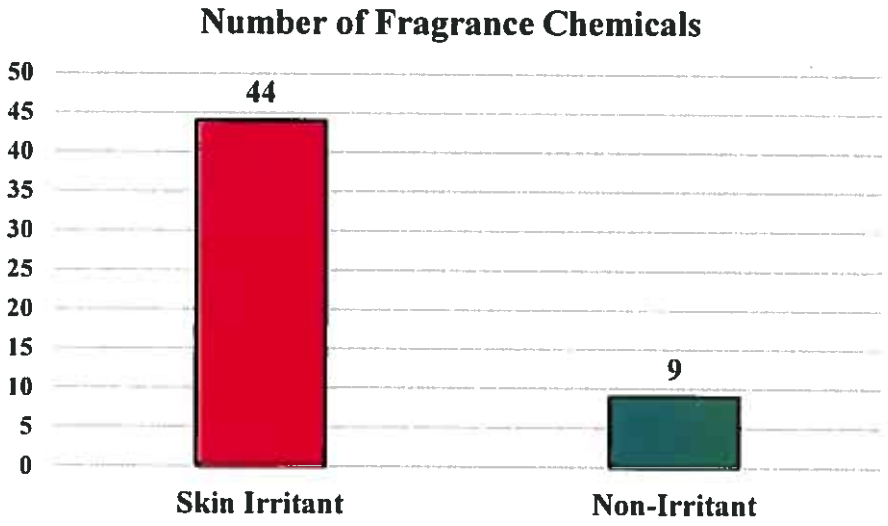
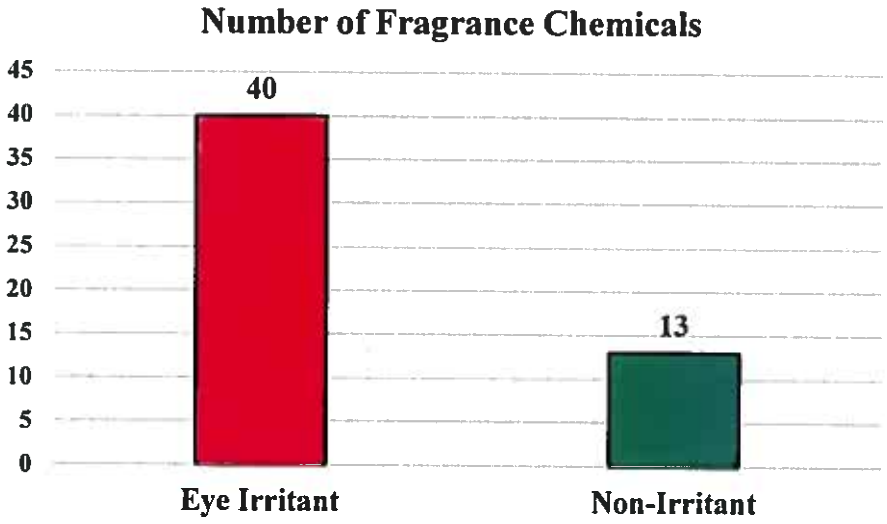


Figure 18 **Fragrance Chemicals Classified as an Eye Irritant**

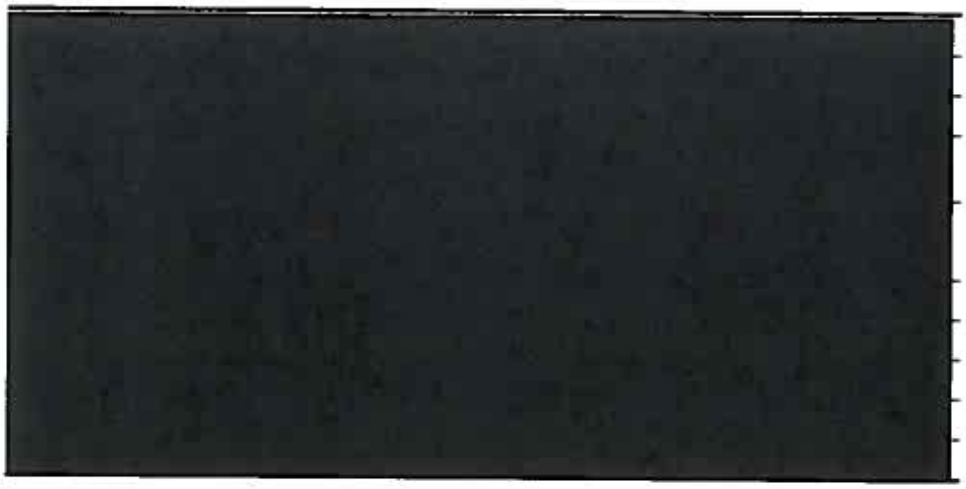


5.5 Fragrance Chemicals Classified As Sensitizers

As described in Section 4.5, the fragrance chemicals were reviewed to identify those that are classified as sensitizers. Of the 53 fragrance chemicals in the Shower to Shower product, 16 fragrance chemicals are classified as sensitizers.

A summary of the findings is provided in Table 18 and a comparison of the number of fragrance chemicals designated as irritants, skin irritants and eye irritants are provided in Figure 19.

Table 18 **Fragrance Chemicals Added to Johnson & Johnson Shower to Shower Product with Sensitization Warnings**



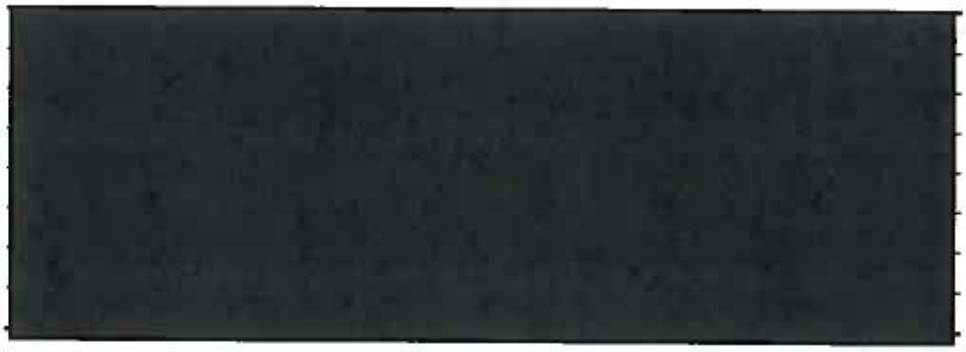
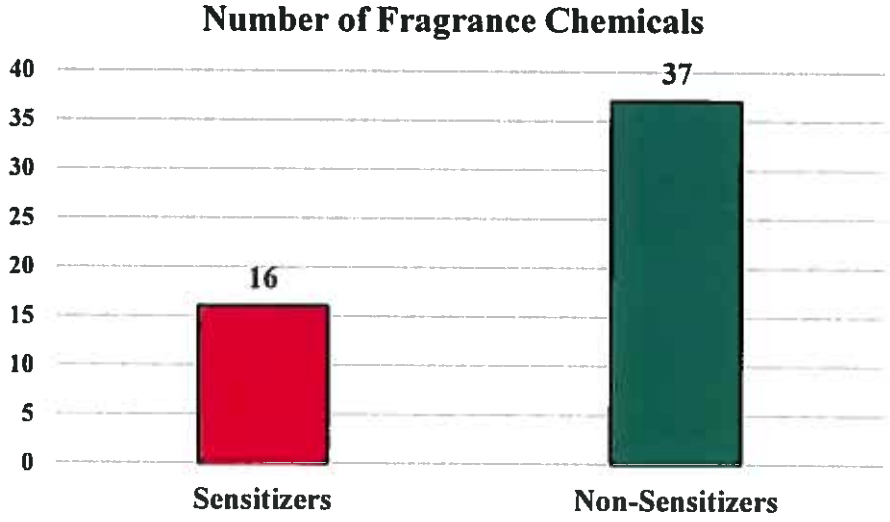


Figure 19 **Number of Fragrance Chemicals Classified as a Sensitization Hazard**



5.6 Fragrance Chemicals Classified As Allergens and or Cause Contact Dermatitis

As described in Section 4.6, the fragrance chemicals in Shower to Shower were reviewed to identify those that are classified as allergens or with literature reports of causing contact dermatitis.

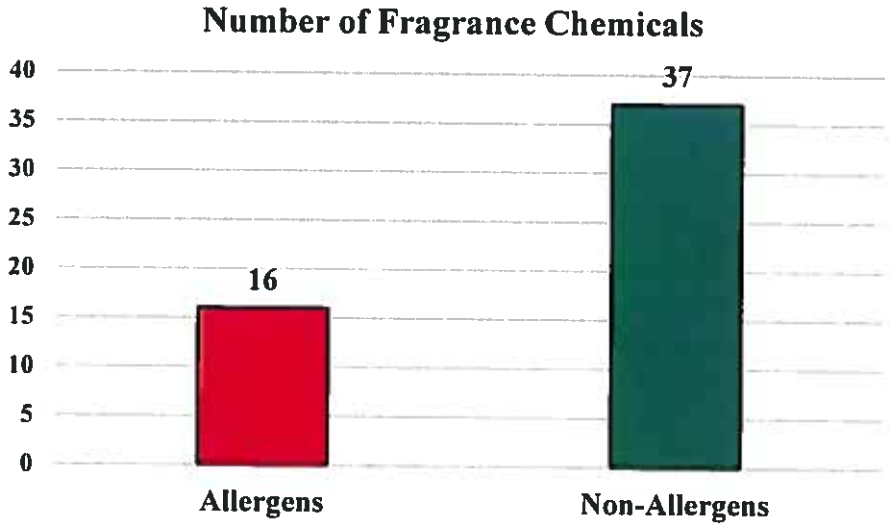
Of the 53 fragrance chemicals in the product, 16 fragrance chemicals are classified as allergens and or cause contact dermatitis.

A summary of the findings is provided in Table 19 and a comparison of the number of fragrance chemicals designated as irritants, skin irritants and eye irritants are provided in Figure 20.

Table 19 **Fragrance Chemicals Added to Johnson & Johnson Shower to Shower Product Classified as Allergens and or Can Cause Contact Dermatitis**

[redacted]

Figure 20 **Fragrance Chemicals Classified as Allergens and or Cause Contact Dermatitis**



5.7 Fragrance Chemicals with IFRA Critical Effects

As described in Section 4.7, the fragrance chemicals in Shower to Shower were reviewed to identify those that are designated with an IFRA Critical Effect.

Of the 53 fragrance chemicals in the product, 15 fragrance chemicals have an IFRA Critical Effect. A summary of the findings is provided in Table 20 and a comparison of the number of fragrance chemicals designated with an IFRA Critical Effect is provided in Figure 21.

Table 20 **Fragrance Chemicals Added to Johnson & Johnson Shower to Shower Product with IFRA Critical Effects**

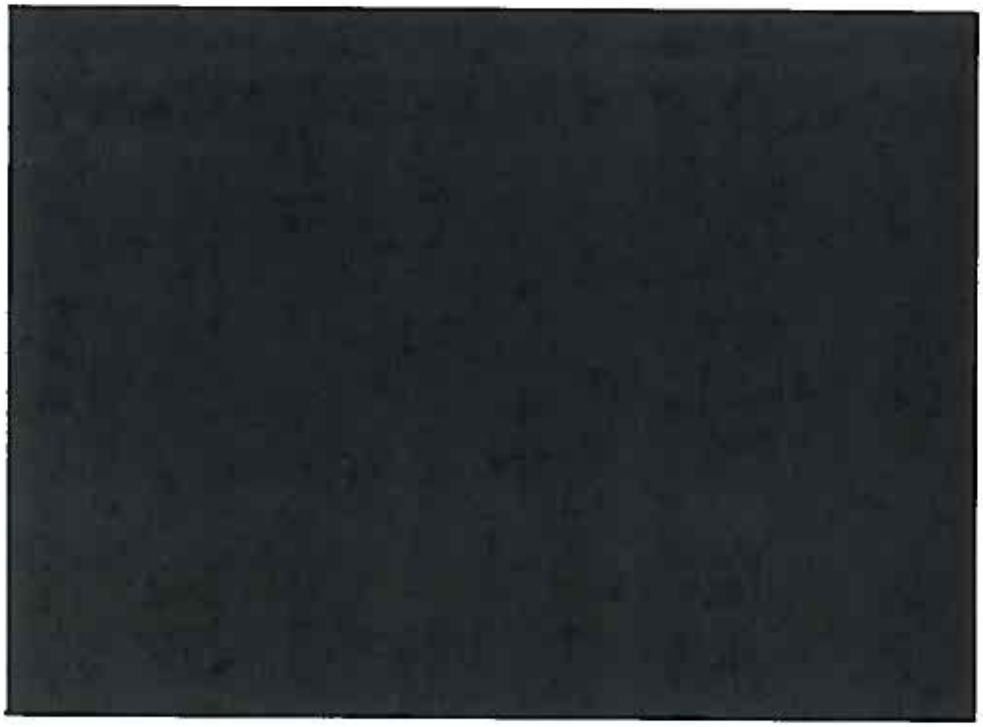
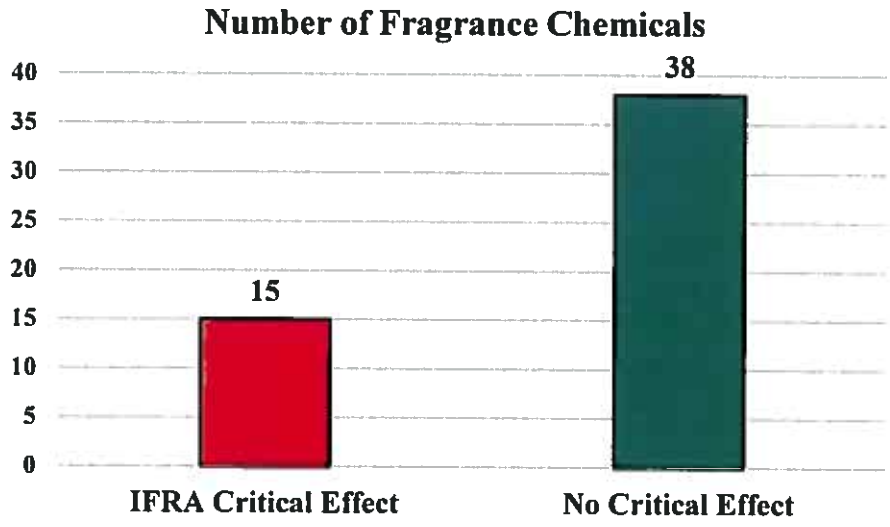


Figure 21 **Fragrance Chemicals with IFRA Critical Effects**



5.8 Fragrance Chemicals with IFRA Category 5 Restrictions

As described in Section 4.8, the fragrance chemicals in Shower to Shower were reviewed to identify those that are designated with a Category 5 Restriction.

Of the 53 fragrance chemicals in the product, 13 fragrance chemicals have a Category 5 Restriction. A summary of the findings is provided in Table 21 and a comparison of the number of fragrance chemicals designated with a Category 5 Restriction is provided in Figure 22.

Table 21 **Fragrance Chemicals Added to Johnson & Johnson Shower to Shower Product with IFRA Category 5 Restriction**

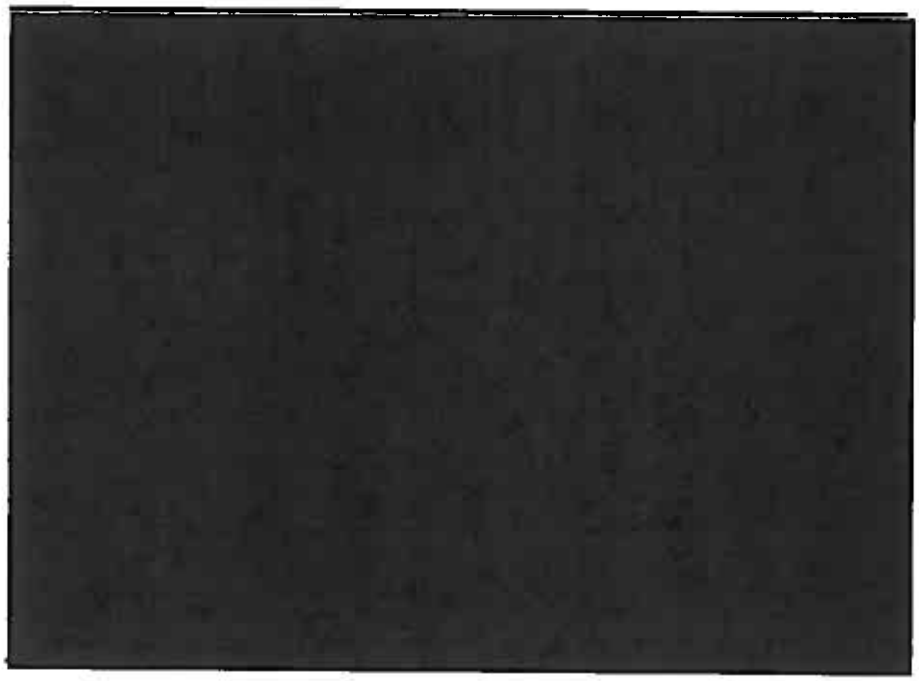
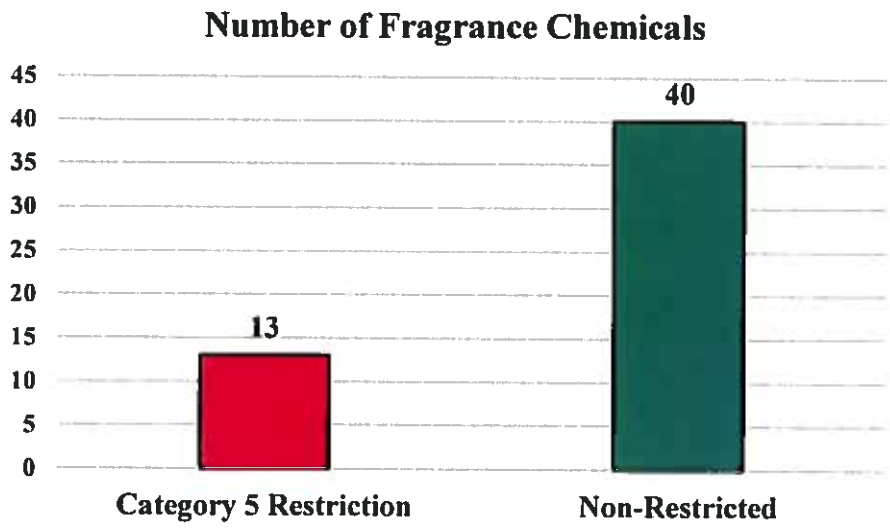


Figure 22 Fragrance Chemicals with a Category 5 Restriction

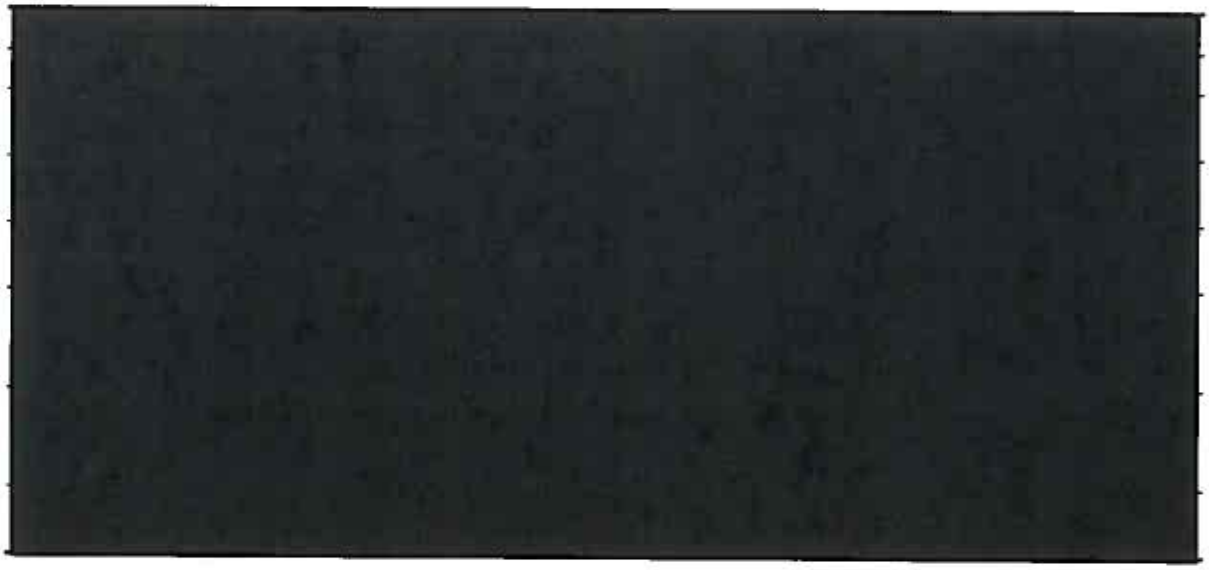


5.9 Fragrance Chemicals with Exposure Limits

As described in Section 4.9, the fragrance chemicals in Shower to Shower were reviewed to identify those that are designated with Exposure Limits.

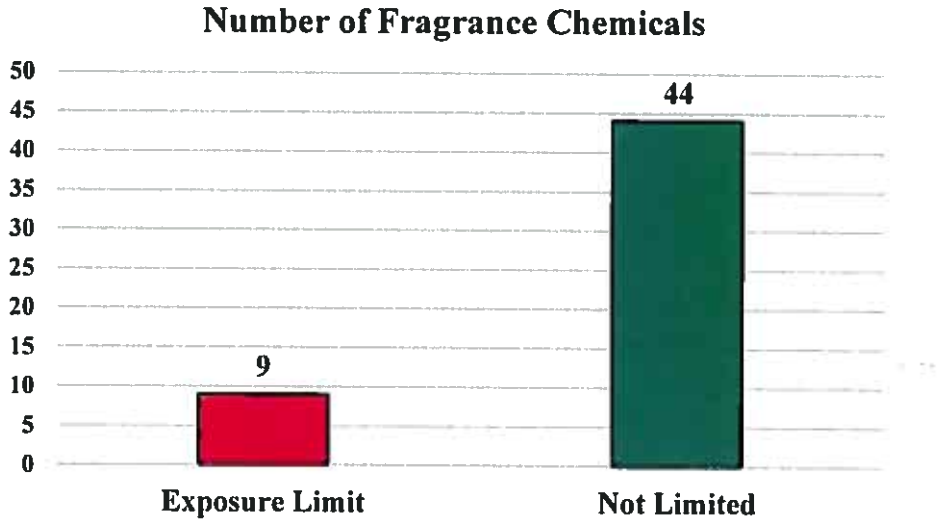
Of the 53 fragrance chemicals in the product, 9 fragrance chemicals have a Exposure Limit. A summary of the findings is provided in Table 22 and a comparison of the number of fragrance chemicals designated with an Exposure Limit is provided in Figure 23.

Table 22 Fragrance Chemicals Added to Johnson & Johnson Shower to Shower Product with Exposure Limits



[redacted]

Figure 23 Fragrance Chemicals with Exposure Limits



5.10 Fragrance Chemicals Listed on the FDA Inactive Ingredient Database (IID)

As described in Section 4.10, the fragrance chemicals in Shower to Shower were reviewed to identify those listed on the FDA IID, including those listed for topical administration (applied to the skin) and vaginal administration.

Of the 53 fragrance chemicals in the product, 11 fragrance chemicals are listed on the FDA IID, 6 are present in approved drug products for topical administration and 2 are present in an approved drug product for vaginal administration.

Table 23 Fragrance Chemicals Added to Johnson & Johnson Baby Powder Product Listed on the FDA IID

[redacted]

[redacted]

Figure 24 **Fragrance Chemicals Listed on the FDA IID**

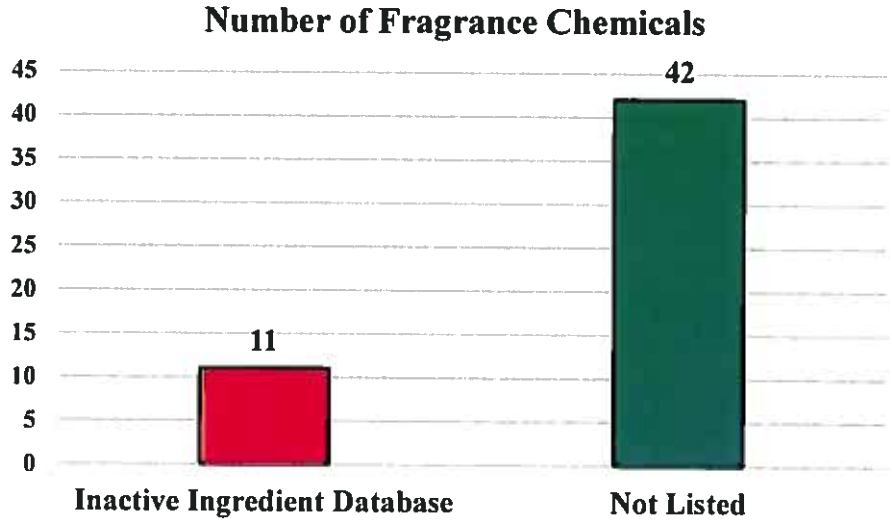


Figure 25 **Fragrance Chemicals Listed on the FDA IID for Topical Administration**

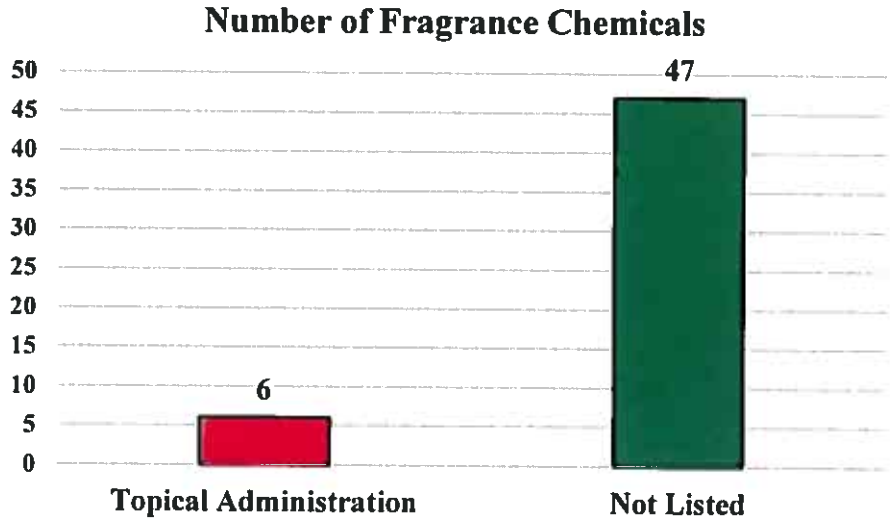
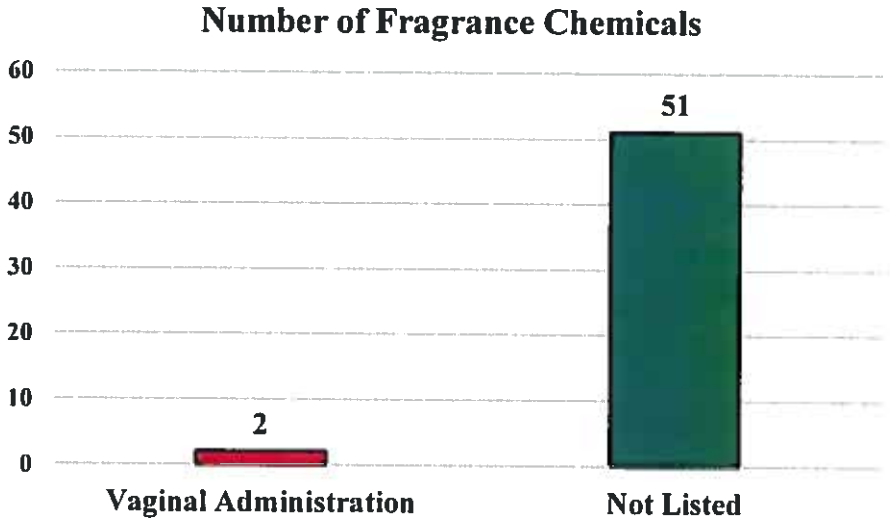


Figure 26 **Fragrance Chemicals Listed on the FDA IID for Vaginal Administration**



6 CONCLUSION AND OPINION

Based on my education, training, and experience in the fields of molecular pharmaceutics, chemistry and drug delivery, and my review of the pertinent information for this matter, I have reached the following conclusions and opinions:

6.1 The fragrance chemicals are not in compliance with governmental and industry standards

This opinion is based upon the following facts:

- Several fragrance chemicals do not have an established governmental or industry standard.
- Myroxylon Pereirae (Balsam Peru) Oil, present in Baby Powder, is prohibited as a fragrance chemical and is not permitted for use on the body.
- Benzene, ethenyl-, also known as Styrene, is not permitted for fragrance or flavor use.
- Copper Chlorophyll, a colorant, is not permitted for cosmetic use by the FDA.
- Methyl Hydrogenated Rosinate is not a fragrance, does not have an IFRA standard and is not listed by CIR.
- Para-cresol is not permitted in cosmetics according to the Cosmetic Ingredient Review Expert Panel.
- Benzophenone is no longer listed in the CFR and has no IFRA Standard.

6.2 The fragrance chemicals in Johnson and Johnson talcum powder products contribute to the inflammatory properties, toxicity, and potential carcinogenicity of the products

This opinion is based upon the following facts:

- Only 1 of the 141 fragrance chemicals in the Baby Powder product have been investigated for safety in the vagina in a product approved by the FDA.
- Only 2 of the 53 chemicals in Shower to Shower have been investigated for safety in the vagina in a product approved by the FDA.
- Several fragrance chemicals are irritants, sensitizers and allergens that can cause inflammation and oxidative stress.
- In vitro and in vivo studies have demonstrated that several fragrance chemicals have biological activity, including reproductive and developmental effects. These studies have been published in peer reviewed scientific journals.
- Four chemicals in Johnson and Johnson's Baby Powder product have been identified by the International Agency for Research on Cancer (IARC) as potential carcinogens: styrene, coumarin, eugenal and d-limone.
- Styrene has been recognized as a carcinogen by multiple governmental regulatory bodies.
- The U.S. Environmental Protection Agency considers p-cresol, also known as 4-methylphenol, to be "possibly carcinogenic".
- p-Cresol was co-carcinogenic and promoted tumors on mouse skin.

- Three fragrance chemicals added to J&J's Shower to Shower talcum product are included in the IARC monographs as possible carcinogens: benzophenone, eugenol and coumarin.
- Benzophenone was recently removed from use in foods by FDA due to histiocytic sarcoma observed in ovaries and uterus, higher incidences of kidney tumors and leukemia in animal studies, and in vivo estrogenic activity.
- Musk ketone is suspected of being a carcinogen, and has been classified as a Category 3 carcinogen by the Scientific Committee on Health and Environmental Risks (SCHER)
- Methyl Hydrogenated Rosinate is present in Baby Powder and Shower to Shower. Methyl Hydrogenated Rosinate is a film former and used to adhere the fragrance chemicals to the talcum powder.
- The safety margins of the 175 fragrance chemicals were determined for foods (oral administration) or cosmetics (topical application to the skin).
- Only 3 fragrance chemicals are present in an approved drug product administered to the vagina according to the FDA IID.
- Assuming that talcum powder migrates through the genital tract, exposure of the female reproductive organs (including vagina, endometrium, fallopian tubes, and ovaries) to talcum powder is an unintended consequence of the perineal application of Johnson's Baby Powder and Shower to Shower products
- Accordingly, in my opinion, the fragrance chemicals in the Johnson & Johnson talcum powder products contribute to the inflammatory properties, toxicity, and potential carcinogenicity of these products.

All opinions in this report are provided to a reasonable degree of scientific certainty. I reserve the right to amend or supplement this repot as more information becomes available.

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APPENDIX A: BABY POWDER FRAGRANCE CHEMICAL REVIEW

REDACTED

ATTORNEYS' EYES ONLY

APPENDIX B: SHOWER TO SHOWER FRAGRANCE CHEMICAL REVIEW

REDACTED

ATTORNEYS' EYES ONLY

APPENDIX C

Currivulum Vitae

Michael M. Crowley, Ph.D.

13305 Council Bluff Drive, Austin, Texas 78727
512-659-6900
mcrowley@theridian.com

I. PERSONAL

Date of Birth:	February 24, 1966
Place of Birth:	Creve Coeur, MO, USA
Citizenship:	United States of America
Marital Status:	Married; Three Children

II. EDUCATION

The University of Texas at Austin, Austin, TX — 1/00 to 4/03
Ph.D. in Molecular Pharmaceutics, supervised by Dr. James W. McGinity,
Dissertation Title: "Physicochemical and Mechanical Characterization of Hot-Melt Extruded Dosage Forms"

Washington University, St. Louis, MO — 8/90 to 12/91
M.A., Organic Chemistry, *Cum Laude*, 3.3 GPA

University of Missouri, St. Louis, MO — 9/87 to 5/90
B.S., Chemistry, *Summa Cum Laude*, 3.88 GPA

III. WORK & RESEARCH EXPERIENCE

Theridian Technologies, LLC
President — **3/09 to Present**

Providing consulting services for drug product development and corporate / business development. Technical consulting services include product and process development, CMC project management, selection and management of CRO's / CMO's, application of proprietary and non-proprietary delivery technologies, scale up and technology transfer, and IP development. Scientific expert for patent litigation. Corporate and business development services include product and platform technology valuation and assessment, due diligence, strategy / tactics / planning, product and technology licensing and asset brokering.

Oticara, Inc. (formerly Oticus Labs, LLC)
Co-Founder — **1/15 to Present**

Specialty pharmaceutical company developing novel treatments for infectious disease.

Texas EnteroSorbents, Inc. ("TxESI")
Board of Directors **6/11 to Present**

TxESI was the first private company funded and owned by Texas A&M University System (TAMUS) based on innovative technology developed at TAMUS. TxESI products and technologies mitigate and/or remove toxins and inflammatory products from numerous animals and in humans. TxESI technologies, when included in food or animal feed, can prevent bacterial and fungal contamination. These unique compositions facilitate the removal of previously absorbed toxins and toxins associated with bacterial death and disease from the gastrointestinal tract.

PharmaForm, LLC
Vice President, Business Development **5/06 to 3/09**

Responsible for new and existing business development activities including management of sales, marketing, advertising and contract generation / negotiation. Contracts include proposals, development / service agreements, term sheets, license agreements and CDA's. Assess resource requirements for new and existing projects. Identify marketing opportunities and represent the company at trade shows and conventions. Identify, generate and coordinate intellectual property applications and filings with internal resources and attorneys. Manage and coordinate company sales, marketing and advertising efforts. Managed 4 employees. Closed $28M in contracts last 2 years, in-licensed 2 drug delivery technologies, executed 2 out-license agreements and 1 option agreement, and increased sales contracts an average of 28% per year and backlog an average of 12% per year.

PharmaForm, LLC
Vice President, Quality Control & Analytical R&D **5/05 to 5/06**

Responsible for management of the Quality Control Laboratory and Analytical Research & Development Laboratory. These labs develop methodology to analyze raw materials, API's, in process samples, bulk and finished product in a GMP environment. Additional scientific responsibilities include studying physical and chemical interaction between the pharmaceutical raw excipients and drug substances, development and validation of stability indicating analytical methodology and development of cleaning methodology to support clinical and commercial manufacturing. Managed 36 employees.

PharmaForm, LLC
Vice President, Drug Delivery Technology & Manufacturing Services **4/03 to 5/05**

Responsible for management of multiple customer oriented drug development projects from pre-formulation to clinical trials and commercial production, including identification of manufacturing equipment and process technology, scale up studies and trouble shooting. Products under development include solid oral dosage forms, transdermal, trans-mucosal, semi-solid and liquids of both small and large compounds. Managed 24 employees. Developed two products resulting in the company's first two out-licensing agreements. Responsible for the technical transfer and contract manufacture of the company's first commercial product and resulting PAI.

The University of Texas at Austin **1/00 to 4/03**
Graduate Student & Teaching Assistant

Responsibilities involved class work and planning experiments in support of a Ph. D. dissertation in Pharmaceutics. Experienced in hot-melt extrusion, wet granulation, extrusion / spheronization, fluidized bed granulating and coating, film coating and tableting. Analytical techniques encompassed USP test methodology including HPLC, GPC, x-ray

diffraction, scanning electron microscopy and differential scanning calorimetry. As lead TA for the undergraduate Compounding Laboratory, teaching responsibilities involved writing quizzes, midterms, finals exams, arranging 22 preparations for the semester, preparing a pre-lab discussion and demonstration each week, and evaluating the students work. Additionally, I supervised two undergraduates as part of an industry sponsored internship.

Mission Pharmacal Co., San Antonio, TX **7/95 to 1/00**
Research & Development, Operations Manager

Responsible for product and process development for both nutritional supplements and drug products (NDA, 505B2, ANDA) in solid oral and topical dosage forms. Duties included pre-formulation, formulation and product development, analytical and physico-chemical characterization, scale-up, packaging engineering, validation and troubleshooting under GMPs. Generated data and documents for CMC section of regulatory filings. Evaluated and reviewed products in stability programs to support development activities, clinical trials and regulatory submissions. Experimental data and reports were presented in technical reports and oral presentations to senior management. Managed 16 - 24 employees.

Warner-Jenkinson Company Inc., St. Louis, MO **1/92 to 7/95**
Chemist, Pharmaceuticals

Managed pharmaceutical projects involving the application of excipients in film coating, tablets, pellets, solutions, suspensions, topicals, printing inks and medical devices. Other responsibilities included writing technical data bulletins, developing analytical methods and product brochures, maintaining regulatory information, determining product pricing, making field service calls and representing the company at trade shows and conventions.

Sigma Chemical Company, St. Louis, MO **5/90 to 8/90**
Analyst, Summer Intern

I worked as a summer intern and analyst in the Product Assay Laboratory. Responsible for all flame emission, atomic absorption and atomic fluorescence spectrometry for the Sigma product line. The instrument was computer interfaced and employed a Zeeman Effect background correction using standard atomization and electrothermal methods. Programmed the computer for statistical analysis of calibration curves, sample preparation and instrumental performance.

University of Missouri, St. Louis, MO **5/89 to 5/90**
Undergraduate Research Associate

The topic of my undergraduate research was the thermodynamics of binding to transferrin. Binding coefficients are needed for the rational design of pharmaceutical chelating agents, which must be able to compete with transferrin in vivo. The binding coefficients were evaluated by direct titration of metal free protein with metals and/or anionic ligands as measured by UV/Vis spectrometry. Nonlinear least squares refinement of the observed data yielded binding coefficients. The results of our research were published in *Inorganic Chemistry*.

Monsanto Co., St. Louis, MO **5/88 to 12/89**
Animal Sciences Division, Formulations Chemistry, Research Analyst

Responsible for generation of data using analytical methods: HPLC, SE-HPLC, atomic absorption, UV/Vis spectrometry, in vitro dissolution, particle size determination by laser light diffraction, viscometry, fluorimetry, moisture content by Karl Fischer and several wet techniques. Trained in GLP/GMP operations and analytical method

validations in support of clinical trials and stability studies for somatotropin proteins. Trained and qualified other analysts in analytical methods, equipment operations and troubleshooting.

IV. PROFESSIONAL MEMBERSHIPS

1. American Association of Pharmaceutical Scientists
   (Sections of Pharmaceutical Technology, Pharmaceutics and Drug Delivery)
2. Controlled Release Society
3. American Chemical Society (past)
4. Licensing Executives Society (past)

V. RESEARCH INTERESTS

1. Development of novel drug delivery systems.
2. Sustained release oral dosage forms and mechanism(s) of drug release.
3. Melt extrusion and thermal processing techniques.
4. Solubility enhancement, particle engineering, microencapsulation and emulsion techniques.
5. Bioadhesive drug delivery systems.
6. Novel controlled release film coating formulations using acrylic and cellulosic polymers.
7. Analytical characterization and stability of active pharmaceutical agents and excipients.

VI. COURSES PRESENTED

1. Pharmaceutics I Laboratory – The University of Texas at Austin.
2. Chemistry I Laboratory – Washington University.

VII. HONORS & AWARDS

2012 "Most Downloaded Manuscript Published in Drug Development & Industrial Pharmacy" Award for M.M. Crowley, F. Zhang, et al, "Pharmaceutical Applications of Hot-Melt Extrusion: Part I", Drug Development and Industrial Pharmacy, 33 (9): 909-926 (2007)
2011 "Most Downloaded Manuscript Published in Drug Development & Industrial Pharmacy" Award for M.M. Crowley, F. Zhang, et al, "Pharmaceutical Applications of Hot-Melt Extrusion: Part I", Drug Development and Industrial Pharmacy, 33 (9): 909-926 (2007)
2002 – 2003 University Continuing Fellow, the University of Texas at Austin
2002 – 2003 American Foundation for Pharmaceutical Education Fellow
2001 – 2002 Texas Excellence in Teaching Award
2001 – 2002 American Society for Quality Control Scholarship
2001 – 2002 American Foundation for Pharmaceutical Education Fellow
1990 – 1991 Washington University Full Tuition Scholarship
1990 – 1991 Washington University Fellow
1988 – 1990 University of Missouri Scholars Scholarship
1990 American Institute of Chemists Outstanding Senior Award
1990 Alan F. Berndt, Ph.D. Outstanding Senior in Chemistry Award
1989 – 1990 Eric G. Brunngraber, Ph.D. Undergraduate Research Fellowship
1989 American Chemical Society Outstanding Chemical Technology Student Award

VIII. CONTRIBUTIONS TO SCIENTIFIC LITERATURE

1. Journal of Pharmaceutical Sciences – referee.
2. Drug Development and Industrial Pharmacy – referee.
3. European Journal of Pharmaceutics and Biopharmaceutics – referee.
4. Journal of Pharmacy and Pharmacology – referee.
5. European Journal of Pharmaceutics – referee.
6. Pharmaceutical Research – referee.
7. International Journal of Pharmaceutics – referee.
8. Journal of Microencapsulation – referee.
9. S.T.P. Pharma Sciences (France) – referee.
10. Pharmaceutical Development and Technology – referee.
11. Journal of Controlled Release – referee.
12. AAPS PharmSciTech – referee.

IX. PUBLICATIONS

1. WR Harris, PK Bali, MM Crowley, "Kinetics of Iron Removal from Monoferric and Cobalt-Labeled Monoferric Transferrins by Diethylenetriaminepenta (methylenephosphonic acid) and Diethylenetriaminepentaacetic Acid", Inorganic Chemistry, 1992; 31: 2700 - 2705.
2. MM Crowley, F Zhang, JJ Koleng, JW McGinity, "Stability of Polyethylene Oxide in Matrix Tablets Prepared by Hot-Melt Extrusion", Biomaterials, 2002; 23(21): 4241 – 4248.
3. MM Crowley, B Schroeder, A Fredersdorf, S Obara, M Talarico, S Kucera, JW McGinity, "Physicochemical Properties and Mechanism of Drug Release from Ethyl Cellulose Matrix Tablets prepared by Direct Compression and Hot-melt Extrusion", International Journal of Pharmaceutics, 2004; 269(2): 509 – 522.
4. MM Crowley, A Fredersdorf, B Schroeder, S Prodduturi, MA Repka, JW McGinity, "The Influence of Guaifenesin and Ketoprofen on the Properties of Hot-melt Extruded Polyethylene Oxide Films", European Journal of Pharmaceutical Science, 2004; 22(5): 409 – 418.
5. S Venkata, S Tumuluri, S Prodduturi, MM Crowley, BA Avery, MA Repka, JW McGinity, "The Use of Near-Infrared Spectroscopy for The Quantitation of An Active In Hot-Melt Extruded Films", Drug Development and Industrial Pharmacy, 2004; 30(5): 505-511.
6. CR Young, MM Crowley, JW McGinity, "Physicochemical properties and film-coating of a melt-extruded and spheronized solid dispersion for pH-dependent drug delivery", Journal of Microencapsulation, 2007; 24(1): 57-71.
7. MM Crowley, F Zhang, MA Repka, S Thumma, SB Upadye, S Kumar, JW McGinity, C Martin, "Pharmaceutical Applications of Hot-Melt Extrusion: Part 1", Drug Delivery & Industrial Pharmacy, 2007; 33(9): 909-926.
8. MA Repka, S Thumma, SB Upadye, S Kumar, MM Crowley, F Zhang, C Martin, JW McGinity, "Pharmaceutical Applications of Hot-Melt Extrusion: Part 2", Drug Delivery & Industrial Pharmacy, 2007; 33(10) 1043-1057.

9. KA Overhoff, R Clayborough, MM Crowley, "Review of the TAIFUN® Multi-dose Dry Powder Inhaler Technology", Drug Delivery & Industrial Pharmacy, 2008; 34(9) 960 – 965.

10. C Berkland, G Laurence, S Lermer and MM Crowley, "An Overview of the NanoCluster Powder Formulation Technology", Pharmaceutical Technology, 2010 34(10) 72-78.

11. T Listro, M Borek, MM Crowley, K Nollenberger, "Analytical Tools & Techniques in Hot Melt Extrusion & Case Studies on Formulation Development & Process Scale-Up" Drug Development & Delivery, 2012 12(7) 36-40.

12. SA. Kucera, MS Zamloot, MM Crowley, LH Burns, N Friedmann and R Barbier. Abuse-deterrent properties of REMOXY® ER, a high-viscosity extended-release oxycodone formulation. Journal of Opioid Management. *In press*.

X. BOOK CHAPTERS

1. M.M. Crowley. "Solutions, Emulsions, Suspensions and Extracts" in Remington: The Science and Practice of Pharmacy, 21st Edition. Edited by R. Hendrickson. Lippincott, Williams & Wilkins (2005).

2. M.M. Crowley. "Solutions, Emulsions, Suspensions and Extracts" in Remington: The Science and Practice of Pharmacy, 22nd Edition. Edited by R. Hendrickson. Pharmaceutical Press, (2013).

3. M.M. Crowley. "Solutions, Emulsions, Suspensions and Extracts" in Remington: Essentials of Pharmaceutics, 1st Edition. Edited by L. Felton. Pharmaceutical Press, (2013).

4. M.M. Crowley. "Pharmaceutical Dosage Forms: Manufacturing and Compounding" in Remington: An Introduction to Pharmacy, 1st Edition. Edited by L.V. Allen. Pharmaceutical Press, (2013).

XI. PRESENTATIONS & INVITED LECTURES

1. CA Signorino, MM Crowley, L Forcellini, "Assessing the Uniformity of Aqueous Film Coatings Applied to Compressed Tablets", Ninth Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, San Diego, CA., November, 1994.

2. MM Crowley, F Zhang, JJ Koleng, JW McGinity, "Evaluation of a Hot-Melt Extrusion Technique using a Hydrophilic Thermal Polymer and Retardant for the Preparation of Extended Release Chlorpheniramine Maleate Tablets", Fourteenth Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Indianapolis, Indiana. October, 2000.

3. MM Crowley, "Properties of Hot-Melt Extruded CPM Tablets Using Hydrophilic Polymers", Seminar, College of Pharmacy Fall 2000 Pharmaceutics Seminar Series, The University of Texas at Austin, Austin, Texas. November, 2000.
4. MM Crowley, "Properties of Potassium Chloride Controlled Release Dosage Forms", Seminar, College of Pharmacy Spring 2001 Pharmaceutics Seminar Series, The University of Texas at Austin, Austin, Texas. April, 2001.

5. KA Overhoff, DP Jones, JR Hunt, LD Bruce, MM Crowley, CR Young, JW McGinity, "Influence of pH, Neutralizing Agent, Storage Temperature and Packaging on the Stability of Methylparaben and Propylparaben in a Hydrophilic Gel", Fifteenth Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Denver, CO. October, 2001.
6. MM Crowley, F Zhang, JJ Koleng, JW McGinity, "The Stability of Polyethylene Oxide in Matrix Tablets Prepared by Hot-Melt Extrusion", Fifteenth Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Denver, CO. October, 2001.
7. MM Crowley, S Obara, JW McGinity, "The Influence of Low Substituted Hydroxypropyl Cellulose on the Properties of Hot-Melt Extruded Tablets, Fifteenth Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Denver, CO. October, 2001.
8. S Prodduturi, MM Crowley, SP Stodghill, MA Repka, "Solid State Characterization of Hot-Melt Extruded Films Containing Clotrimazole", Sixteenth Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Toronto, Ontario, Canada. October, 2002.

9. MM Crowley, A Fredersdorf, B Schröder, S Obara, S Kucera, JW McGinity, "Properties of Ethyl Cellulose Matrix Tablets", Sixteenth Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Toronto, Ontario, Canada. October, 2002.

10. MM Crowley, MA Repka, B Avery, V Tumuluri, S. Prodduturi, "The Use Of Near-infrared Spectroscopy For The Quantitation Of An Active In A Hot-melt Extruded Film" Seventeenth Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, Utah. October, 2003.

11. S Prodduturi, MM Crowley, MA Repka, "Influence Of Water-soluble Polymeric Matrix Carriers On The Bioadhesive And Release Properties Of Hot-melt Extruded Films Containing A Water Insoluble Drug", Seventeenth Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, Utah. October, 2003.

12. M Kemper, I Lewis, S. Prodduturi, V. Tumuluri, MM Crowley, B. Avery, MA Repka, "The Use Of Off-line And On-line Raman Spectroscopy To Quantify Ketoprofen And Clotrimazole In Hot-melt Extruded Film Formulations", Seventeenth Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists National Meeting, Salt Lake City, Utah. October, 2003.

13. JW McGinity, CR Young, M Cerea, MM Crowley, "Properties Of Film-coated Polyethylene Oxide Pellets Prepared By A Hot-melt Extrusion And Spheronization Process", Seventeenth Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists National Meeting, Salt Lake City, Utah. October, 2003.

14. J.W. McGinity, CR Young, M Cerea, MM Crowley, C Dietzsch, T. Farrell, K. Fegely, "Properties Of Acryl-eze® Matrix Tablets Prepared Using A Hot-melt Extrusion Process", Seventeenth Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists National Meeting, Salt Lake City, Utah. October, 2003.

15. C. Dietzsche, D. Sauer, CR Young, MM Crowley, J.W. McGinity, "Physicochemical Properties of Film-Coated Melt-Extruded Pellets", Proceedings of the 15th International Symposium on Microencapsulation, Parma, Italy. September, 2005.

16. Pharmaceutical Applications of Hot-Melt Extrusion, Leistritz Pharmaceutical Extrusion Seminar, Bridgewater, New Jersey. June, 2007.

17. "Pharmaceutical Applications of Hot-Melt Extrusion", Proceedings of the 12th Annual Drug Delivery Technologies & Deal-Making, New Brunswick, New Jersey. September, 2007.

18. Drug Delivery Executive Interview, Drug Delivery Technology, April, 2008 Volume 8, Number 4, pages 50 – 52.

19. "Physical and Chemical Properties of Hot-Melt Extruded Dosage Forms", Leistritz Pharmaceutical Extrusion Seminar, Bridgewater, New Jersey. June, 2008.

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